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NEWS THIS MONTH

Class I Recalls Surge To Highest Point Ever; FDA Not Sure Why

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The number of high-risk Class I medical device recalls skyrocketed to its highest point ever last year, leaving FDA officials to ponder what could have caused the dramatic upswing.

Class I recalls rose from 23 in 2009 to 51 in 2010, a 122-percent increase. Previously, 2004 and 2005 held the record for the largest number of Class I recalls, with 26 posted each of those two years. (*See chart, p. 5.*)

"I can't answer why the increase occurred," said Armando Zamora, leader of FDA's Recall Operations Team. "Recalls are dynamic. We don't know what will cause one, and we don't know the severity of one or the risk associated with one until we're informed about it."

Class I is FDA's most serious recall category, reserved for situations where the agency believes patients face a reasonable probability of serious injury or death from use of the defective products.

BD and Cardiac Science tied for having the most Class I recalls of any company in 2010. BD's three Class I's were related to ***Q-Syte*** and ***Acacia*** infusion extension sets, ***Nexiva*** catheter systems, and various trays and kits, while Cardiac Science's automated external defibrillators (AEDs) accounted for its three Class I recalls. (*See chart, p. 7.*)

Other notable Class I recalls last year involved ***LifePak*** external defibrillator/monitors made by Physio-Control, dialysis systems and infusion pumps made by Baxter, and Hospira's ***Symbiq*** one- and two-channel infusers.

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In Their Words

"There are a lot more devices out there that are really aging, and I think that is going to lead to more recalls – and some serious recalls. I really think manufacturers need to get a hold on this reliability issue, because I think it's going to hurt them."

– Denise Dion, senior regulatory consultant, EduQuest, and former FDA investigator

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Class I Recalls. . .

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FDA can typically point to a particular component or device that causes a jump in Class I recalls because it is used in so many finished products, such as "coring" Huber needles in 2009 or counterfeit glucose test strips in 2007 ("The Silver Sheet," February 2010 and February 2008, respectively).

However, the types of devices involved in Class I recalls in 2010 were a hodgepodge of products, from the expected (infusion pumps; AEDs) to the more curious (antimicrobial susceptibility cards; saline syringes).

"We wonder about those recall numbers, as well. It's difficult to say what prompted an increase like that," Larry Spears, deputy director of regulatory affairs in CDRH's Office of Compliance, told "The Silver Sheet."

"It can certainly be a combination of different factors," he said. "There are clearly more complex devices going on the market, so that could be part of it. And there are more companies. The registration numbers go up and so does the distribution of certain products. So it's really hard to say."

Overall recalls also rose in calendar year 2010. Manufacturers initiated a total of 717 device recalls last year, up 15 percent from 2009, when 626 recalls were logged. For its 2010 figures, "The Silver Sheet" counted device recalls issued during the calendar year. (*See chart, p. 11.*)

According to FDA fiscal-year figures, there were 876 device recalls in 2010 and 776 in 2009.

FDA's Spears is confident that Commissioner Margaret Hamburg's enforcement approach to recalls has had an effect on industry and the agency.

In late 2009, FDA Commissioner Margaret Hamburg instructed agency staff to conduct inspections promptly after product recalls occur and to respond rapidly to any violations that jeopardize public health ("The Silver Sheet" December 2009).

Zamora suspects that Hamburg's edict may be one reason why the number of recalls increased in 2010.

"Certainly one of the initiatives was for the agency to follow up enforcement-wise, with recalls being included in that bucket, so to speak," Zamora told "The Silver Sheet." "But I couldn't tell you with certainty if there is a correlation with those initiatives and the reason for the increase and spike of these recalls."

Nevertheless, Spears is confident that Hamburg's enforcement approach to recalls has had an effect on industry and FDA.

"I think when you look at the commissioner's enforcement initiative and the things that are associated with that, it does point to the fact that we're going to be looking more closely at recalls, and therefore I think we're going to be seeing more recalls than we did before," he said.

Manufacturers "certainly heard what the commissioner said, and obviously when there is an increased focus on enforcement and [firms are] beginning to see enforcement actions – such as warning letters – pretty actively pub-

licized, I think that gets the attention of industry that FDA is looking more closely. I think it definitely has in an impact."

Denise Dion, senior regulatory consultant for EduQuest in Hyattstown, Md., and a former FDA investigator, suggests that the number of Class I's and the overall number of recalls rose because companies are being more cautious when weighing the risk of a recall.

"Manufacturers are being more conservative, but not to cover their butts from FDA enforcement, but rather because I think they realize that there is a need for them to take a more conservative approach, given not just the FDA's mood, but consumer mood," she said.

"Consumers overall are really concerned about products and how manufacturers deal with recalls, and I think they want responsiveness from the manufacturers," Dion said. "Customers saw what happened when Toyota didn't do the right thing" when it failed to recall cars that had acceleration problems.

It's also about the firm maintaining a good reputation, she said.

"What manufacturers care about is that their customers keep spending money," Dion said. "So what they're doing is trying to regain and hold onto whatever trust they can because in these economic times, if you lose the trust of your customers, then you've lost everything."

It should come as no surprise that larger firms conducted the most recalls last year: Stryker, Philips, Beckman Coulter, Siemens, General Electric, and Biomet. (*See complete list of 2010 recalls, p. 14*).

Philips and Stryker led the pack with 30 recalls each in 2010. Philips has seen its number of recalls rise over the past few years (19 in 2009 and 23 in 2008), while Stryker's recalls have fallen (39 in '09 and 45 in '08).

Rounding out the top six recalling firms for 2010: Beckman Coulter, which posted 24 recalls in 2010, four in 2009 and five in 2008; Siemens, with 22 in 2010, 30 in 2009 and 46 in 2008; General Electric, with 20 in 2010, 32 in 2009 and 35 in 2008; and Biomet with 16 in 2010, 13 in 2009 and 24 in 2008.

On Feb. 7, manufacturer Danaher announced a definitive agreement to buy Beckman Coulter. Danaher said one of its priorities for Beckman Coulter includes completing quality control fixes already underway at the firm.

Centrifuges To Blame For Two Class I Recalls

Two of the more notable Class I recalls in 2010 involved centrifuges, which are low-risk, Class I laboratory instruments.

"Usually when we look at IVD [in vitro diagnostic] recalls, we're looking for the risk profile created by a false test result that can harm a patient," said Alberto Gutierrez, director of FDA's Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD).

However, when it came to the two Class I recalls for centrifuges, "the issue was the safety of the laboratorians," he said.

FDA Recall Classifications

Class I: There is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

Class II: Use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences, or the probability of serious adverse health consequences is remote.

Class III: Use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Mikro and ***Haematokrit*** centrifuges manufactured by Andreas Hettich and the ***Express 4*** horizontal centrifuge made by StatSpin were the subject of the two recalls.

In those cases, the centrifuge rotor cracked and exploded outside of the centrifuge, spewing potentially dangerous projectiles.

"They are tabletop centrifuges that have probably been in the laboratories for several years – about 10 years or maybe longer than that. It is not unusual for centrifuge rotors to fail at some point," Gutierrez told "The Silver Sheet."

"If you go to a lab, they usually have big centrifuges that are encased in metal, or they're made in such a way that if the rotor fails, the pieces are contained within and there is no problem," he said. "But in both of these Class I cases, the top [of the centrifuge] failed, and the rotor then sprayed in the laboratories, causing potential harm to the people working in the lab. So these were a different type of recall for us."

Gutierrez said the age of the centrifuge rotors likely played a part in the explosions. However, he is not ruling out design flaws.

In the meantime, OIVD has reached out to laboratories across the nation to let them know about the potential centrifuge dangers.

"Manufacturers have a tendency to keep servicing devices well past their expected shelf life, and I think they sometimes have a lack of understanding of the real reliability of their devices," EduQuest's Dion says.

"We put a safety notice out and we let laboratorians know that this is an area that they need to be aware of and concerned with, and that they should keep an eye on the rotors, and that if they're seeing issues, they should change the rotors and contact the manufacturers," Gutierrez said.

As for the manufacturers of the centrifuges, "we have not done as much," he said. "It's a little difficult because a lot of these centrifuges are Class I devices, and it's not always easy

for us to know exactly where they are. Sometimes they're made by small companies in small batches and were sold many years ago."

Consultant Dion said she isn't surprised by the Class I centrifuge recalls because many hospitals and other health care organizations are using extremely old devices.

"Some of my clients have a lot of recalls on products that are well past their expected shelf life," she said. "Manufacturers have a tendency to keep servicing devices well past their expected shelf life, and I think they sometimes have a lack of understanding of the real reliability of their devices."

For example, "even if a device has been in the market for only three years, that device probably only has a two-year shelf life, but they keep limping them along, and part of that is because the manufacturers will continue to service them because they don't want to lose the money, and then on top of that, the hospitals and doctors don't want to buy new devices because they don't have any money. So it's a vicious circle," Dion said.

"There are a lot more devices out there that are really aging, and I think that is going to lead to more recalls – and some serious recalls – because once a device gets really old, it can break in ways that would otherwise not happen if it was a younger device," she said.

"I really think manufacturers need to get a hold on this reliability issue, because I think it's going to hurt them."

When Class I Devices Cause High-Risk Recalls

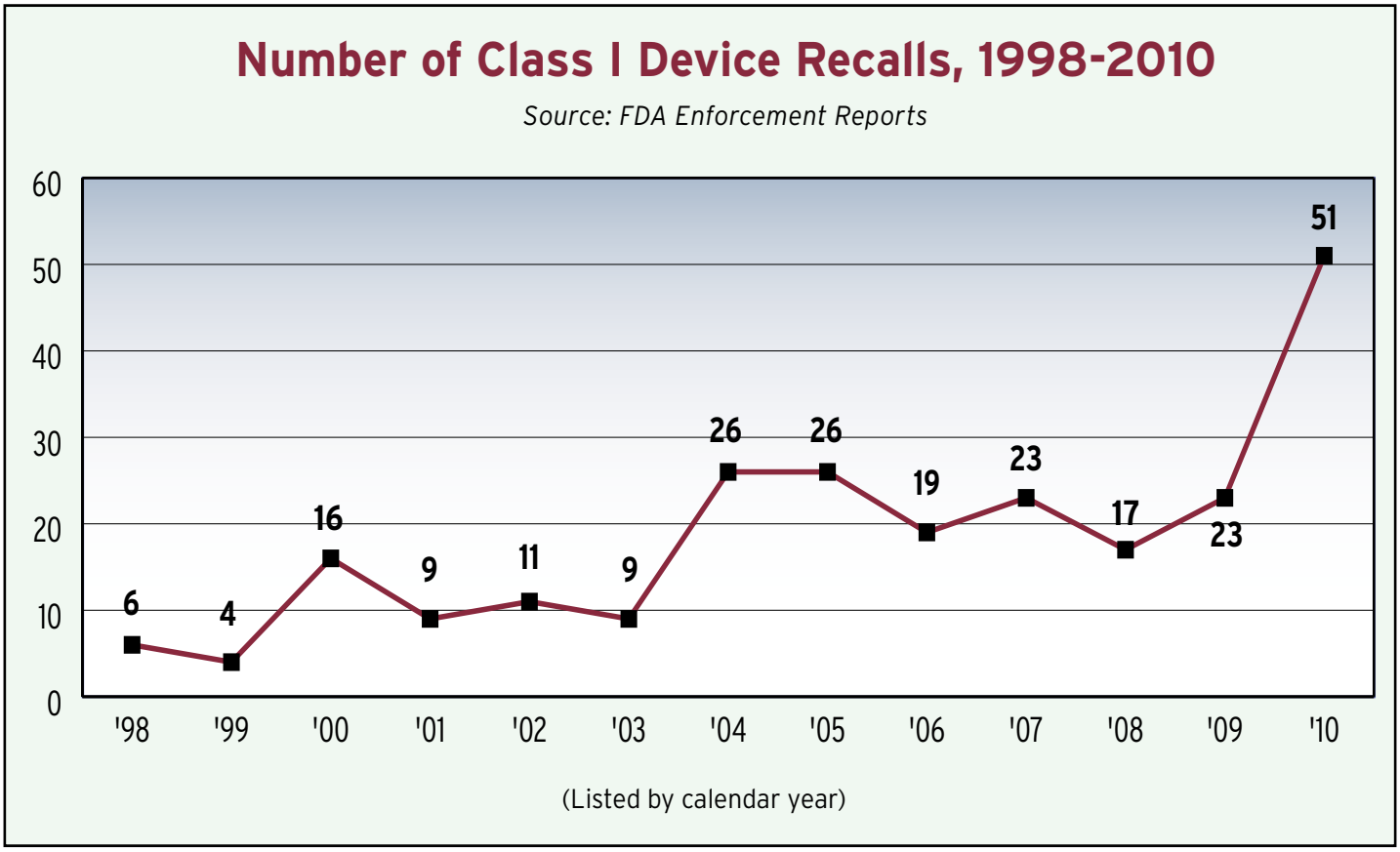
Laboratory centrifuges are low-risk, Class I devices, but what would FDA do if a trend emerged that showed that they were causing more and more high-risk, Class I recalls?

"Clearly if we are seeing either changes in the way products are being used or changes in the product risk profiles, we [will look] to see whether we need to up-classify or whether we need to put special controls in place," OIVD's Gutierrez said.

Centrifuges were just one device type that was evaluated after passage of the Medical Device Amendments of 1976, when an FDA panel reviewed products to determine their risk profile and classification.

"When the risk profile was created [in 1976], I don't think they probably thought about the physical risks that the centrifuges could pose," Gutierrez said. Rather, "I think they were considering risk when it came to negative or positive IVD test results – what the possibility was that the device could cause problems in the laboratory in that sense.

"So that makes this current problem a little different," he continued. "I'm not sure that the problems that we're seeing now will lead us to an up-classification [to a higher-risk Class II], but maybe we have to think about what we can to do to make sure that the industry understands what the issues are and what it needs to do to make sure that the centrifuges don't put people at risk."



Obviously with FDA's limited resources, manufacturers of Class I products are not going to be inspected as often as makers of high-risk Class III devices.

"A lower-risk device, while they will be inspected, they're typically not going to be inspected as often, provided the company has demonstrated that they're in compliance," CDRH's Spears said.

However, if the firm "has a lot of compliance problems, that's different," he said. "So if we're not paying as much attention to them in terms of inspections, then when we do find a situation where there is a recall that actually becomes a [high-risk] Class I recall, then it's certainly going to get our attention."

"It's fairly rare that we would see a Class I device that would result in a Class I recall. But when it does occur, it certainly gets our attention," FDA's Spears says.

"We certainly have the option of making changes in the classification of a device. We have done that at different times where we have up-classified and down-classified. As we get new information on any classification of a device, we can certainly make those adjustments and changes," Spears said.

"It's fairly rare that we would see a Class I device that would result in a Class I recall. But when it does occur, it certainly gets our attention," he said. "If it's causing a serious problem, then what needs to be done? So that would be one of the options on the table – to look at changing the classification for that device."

Consultant Dion isn't holding her breath, however.

"I doubt that FDA would ever up-classify a centrifuge," she said. "The agency has a tendency to spend more time down-classifying than they do considering an up-classification. Plus, you wouldn't get the medical community behind FDA to change the classification of a centrifuge. I doubt that there is any real fix for it, because you're not going to get people to say that a centrifuge is a high-risk device."

Nevertheless, there are many low-risk devices that can cause high-risk Class I recalls.

"A lot of Class I devices do have some of the highest risks associated with their use," Dion said. "Consider a patient lift, which is a Class I device. People have died from being dropped from a patient lift. So some of the highest risks to people can be associated with low-risk devices.

"There are very low-risk devices that have a high risk associated with their use because of the patient population or just because of the way they're used," she added. "Some of these products were grandfathered in at certain risk classifications [in 1976]. People have been harmed by patient lifts since the beginning, and I've never seen FDA change that device's classification, and I doubt it ever will."

2011 Recall Priorities

CDRH's 2011 strategic priorities report, released Jan. 19, notes these device recall goals for the coming year:

- **By March 31, 2011, the center will develop strategies to improve notification about and classification of recalls;**
- **By Oct. 31, 2011, CDRH will begin implementation of the identified strategies; and**
- **By Nov. 30, 2011, CDRH will enhance the efficiency and clarity of medical device recall processes.**

Role Of FDA Staffers In Class I Uptick?

There is some speculation that the rise in Class I recalls is related to FDA's hiring of many new staffers over the past few years to replace retiring officials.

"FDA has hired a lot of new people, and a lot of these people are now in the position of determining things about recalls, and in a lot of districts, the new recall coordinator has only been on the job for less than a year," consultant and former FDA staffer Dion told "The Silver Sheet."

Further, Michael Verdi, the new director of executive operations staff at FDA's Office of Regulatory Affairs (ORA), "came from CDRH's Office of Compliance, and he happens to be a little on the hawkish side when it comes to devices," Dion said. "He tends to be more conservative than his predecessor."

Verdi previously served as the device center's senior recall coordinator. ORA is the lead office for all of the agency's field activities.

"So companies are spending more time talking to their district office about recalls, and because those FDA staffers in the districts tend to be less experienced, they rely heavily on talking to CDRH and Michael Verdi," she said.

The new FDA staffers "are being tougher across the board because they are less experienced. When you have less-experienced people, they tend to be more conservative. They may think a certain recall is really bad, but perhaps people who have done the job for a long time might say, 'Oh, actually, in the scheme of things, this recall is not so bad,'" Dion said.

For example, if a company conducts a recall and decides to label it as Class II, the agency staffers may come back to the firm and explain that they think the recall should be categorized as Class I.

"Manufacturers are doing what they need to do and reporting their recalls, and then at FDA they will sometimes have a tendency to classify things as a Class I rather than a Class II, and

2010 Class I Recalls

Manufacturer / Product	Why Was The Product Recalled?
Accellent's ***EndoClamp*** aortic catheter	Spontaneous balloon rupture during use of the product.
Andreas Hettich's ***Mikro*** and ***Haematokrit*** centrifuges	The centrifuge rotor may crack, break and explode outside of the centrifuge.
AngioScore's ***AngioSculpt*** percutaneous transluminal coronary angioplasty catheter	Separations of the catheter shaft at the guide wire exit port have occurred during treatment of coronary artery stenosis. Fragments of the catheter may become lodged in coronary arteries, resulting in serious patient outcomes, requiring emergency coronary bypass surgery and medical intervention to remove the retained device fragments.
Arrow International's ***MAC*** two-lumen central venous access kit; percutaneous sheath introducer kit; multi-lumen central venous catheterization kit; two-lumen central venous catheterization kit	***Q-Syte*** component contained in kits was recalled by manufacturer due to the potential for embolism if used with a central venous catheter.
Arrow International's intravenous administration sets and accessories	Sterility may be compromised.
Atek Medical Manufacturing's ***Octopus Nuvo*** tissue stabilizer	The collet may fracture, causing immediate separation of the head link from the shaft of the device. The resulting potential hazards are that fragments of the collet could fall into the patient's chest cavity and/or damage the heart tissue.
B. Braun's ***addEASE*** binary connector	During insertion, fragmentation of the PAB container stopper may occur, resulting in a small amount of visible particulates in the solution.
Baxter's ***HomeChoice*** and ***HomeChoice Pro*** automated peritoneal dialysis systems	Potential overfill of the peritoneal cavity, also referred to as increased intraperitoneal volume (IIPV). IIPV can result in serious injury or death.
Baxter's ***Colleague*** single-and triple-channel volumetric infusion pumps	The FDA sent a letter to Baxter on April 30, 2010, ordering the company to recall and destroy all models of its ***Colleague*** volumetric infusion pumps currently in use in the United States. FDA determined that this action was necessary because Baxter failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague pumps still in use.
BD's ***Q-Syte*** split-septum, extension set, and vial access adapter; ***Acacia*** extension sets	Manufacturing defect may allow air entry into a central venous catheter, possibly resulting in an air embolism.
BD's ***Q-Syte*** split-septum, extension set, and vial access adapter; ***Acacia*** extension sets; ***Nexiva*** catheter systems	Manufacturing defect may allow air entry into a central venous catheter, possibly resulting in an air embolism.
BD's I.V. start bundle kit; venous access tray; dialysis kit	Manufacturing defect may allow air entry into a central venous catheter, possibly resulting in an air embolism.
Beckman Coulter's ***UniCel DxC Synchron*** clinical systems	Excessive buildup of protein, bacteria and sample tube additives in the ISE flow cell may cause erroneous NA (sodium) results.
bioMérieux's ***Vitek 2*** gram negative susceptibility card	The piperacillin/tazobactam drug on the antimicrobial susceptibility cards is providing false susceptibility and false resistance results for *E. coli*; the same drug is providing false susceptibility results for *Klebsiella*.
Cardiac Science's ***Powerheart*** and ***CardioVive*** automated external defibrillators	Certain models may not have received adequate electrical safety testing prior to being shipped from the factory.
Cardiac Science's ***Powerheart***, ***Responder*** and ***CardioVive*** automated external defibrillators	A component of the device may fail during a rescue attempt and will not be able to deliver therapy.

Manufacturer / Product	Why Was The Product Recalled?
Cardiac Science's ***Powerheart***, ***Responder***, ***CardioVive*** and ***CardioLife*** automated external defibrillators	Potential for devices to not deliver therapy.
CareFusion's ***Alaris*** PC unit	Under certain wireless network conditions, a communication error can occur, which freezes the PC unit screen, resulting in a delay of therapy.
Centurion Medical Products' ***Preemie*** packs; full-term meconium packs	Pediatric tracheal tubes used in the kits were manufactured with an internal diameter smaller than indicated in the label, which could result in an inability to remove secretions and cause partial or complete obstruction of the airway.
Cepheid's ***Xpert*** blood culture test	The firm is receiving reports of inaccurate results, which may result in delay of care for seriously ill patients.
Cook's ***Ciaglia Blue Rhino G2*** advanced percutaneous tracheostomy introducer sets and trays	Set and/or tray products include a tracheostomy tube component that has been associated with cuff leakage.
Datex-Ohmeda's ***Aisys*** and ***Avance*** anesthesia systems	The control board wiring harness may have a defect, which can cause the machine to unexpectedly shut down, terminating ventilation, anesthetic delivery and potentially patient monitoring.
Defibtech's ***Lifeline*** and ***ReviveR*** semiautomatic external defibrillators	When used with an affected battery pack, the AED may falsely detect an error condition, cancel the charge and not provide therapy.
Ev3's ***TrailBlazer*** support catheter	Catheter may crack near the radiopaque marker band at the distal end of the device during use. Cracking of the catheter shaft in this location can result in material separation and potential embolization.
Excelsior Medical's disposable syringe with normal saline	There is the potential for a dimensional issue, causing leakage and/or loss of sterility.
Exelint International's pump-fill kit	Huber needles included in the pump-fill kits are labeled as non-coring, but they could core 60% to 72% of the time.
Gyrus Medical's ***Micron*** bobbin vent tube	Product may have been shipped without being sterilized.
Hospira's ***Symbiq*** one- and two-channel infusers	The infusion pump fails to detect air-in-line conditions during operation.
Hospira's ***Symbiq*** one- and two-channel infusers	Motor-encoder failures in the pumping mechanism cause the infuser to cease operation during infusion therapy, resulting in delay or interruption of infusion therapy.
INO Therapeutics' ***Ikaria Inomax DS*** drug delivery system	The pressure switch may fail, which may interrupt or delay the administration of Inomax (nitric oxide) for inhalation to patients.
Integra LifeSciences' ***NeuroBalloon*** catheter	Catheters have the potential to improperly inflate or deflate under certain conditions.
Medical Product Specialist's I.V. sets with small and macro bores	A manufacturing deviation could cause the product to not function properly, possibly resulting in an air embolism.
MMJ's ***Shiley*** tracheostomy tubes	Inflatable cuff tracheostomy tubes may leak air, resulting in inadequate ventilation.
Multi-Med's winged administration set; Huber needles	Huber needles may core and result in port leakage or emboli being flushed out of the port.
Multi-Med's Huber needles	An FDA sample determined that the needles were coring.

Manufacturer / Product	Why Was The Product Recalled?
Nikkiso Medical Systems' ***Aquarius*** system	When a certain level of fluid imbalance is detected, the ***Aquarius*** will trigger an alarm. However, users are able to override this alarm and continue therapy. By repeatedly overriding the balance alarm without solving the issue (closed clamp, kinked line, etc.), it is possible to remove too much fluid from, or replace too much fluid to, the patient
Nissho Insurance Services' Huber needles and infusion sets	Non-coring needles, when inserted into an implanted port, were shown to core the silicone port's septum.
Physio-Control's biphasic ***LifePak 15*** defibrillator/monitor	Potential for the device to power off and on by itself, or to power off by itself, requiring the operator to turn it back on. Or, the device doesn't turn off.
Physio-Control's ***LifePak 20*** defibrillator/monitor	A failure on the power-supply assembly can result in either "No DC power" or "No DC or AC power." A failure of DC battery power can result in a delay of defibrillation therapy if no AC line power is available; therefore, the device will not operate.
Pointe Scientific's liquid glucose (HEXO) reagent set	The product fails to maintain a linearity specification of 500 mg/dL.
Ram Medical's Bard mesh monofilament knitted polypropylene	Counterfeit product was mixed with authentic product.
SCC Soft Computer's ***SoftLab*** Mic ASCII software	When a test is being verified, the wrong (expired) ranges may be associated to that test result, causing an incorrect flag to be posted for that test result.
Sigma's ***Spectrum*** volumetric infusion pump	Pumps have the potential to fail, causing inaccurate flow conditions during use. These conditions range from back-flow to free-flow, which could result in over-infusion.
St. Jude Medical's ***Engage TR*** introducer	Introducers have the potential for a partial or complete separation of the shaft (sheath) from the hub, or a material break in the hub assembly just distal to the hemostasis seal. If either of these were to occur during use, it is likely that fluids would leak around the introducer hub and strain relief.
StatSpin's ***Express 4*** horizontal centrifuge	The centrifuge shield micro-switch failed due to damage, and the unit opened and ejected pieces.
Stryker's ***Navigation System II*** CART and PC SPC-1 assembly	Multiple software-related malfunctions may occur. The device may suddenly stop working, the screen may freeze, the screen may update very slowly, the unit may not respond to user input, or the unit may respond to the user very slowly.
Synthes' ***TI Synex II*** central body	There may be a loss of device height.
Teleflex Medical's Hudson RCI ***AQUA+ Flex***	The patient end of the connector on the flex tube may not fit securely within the endotracheal tube connector, thereby disconnecting from the endotracheal tube. A disconnect in ventilator-dependent patients without prompt response to the alarm could lead to hypoxia, organ failure or cardio-respiratory arrest.
Thomas Medical Products' ***Safesheath*** coronary sinus guide hemostatic tear away introducer system	Radiopaque sheath tip may fracture.
WalkMed's ***Triton*** pole mount infusion pump	Pump door may be in a near-shut position, but unlatched, and the "Door Open" alarm may not sound.
Westmed's ***BagEasy*** manual resuscitation devices	There is a potential for disconnection at the patient port retention ring assembly.

(Source: FDA Enforcement Reports)

some of that is just because the agency is being a lot more conservative, and that happens when you have a turnover in staff," Dion said.

Products FDA Is Watching In 2011

Prognosticating about device types that will likely be recalled over the coming year can prove tricky, but for CDRH it's like déjà vu all over again.

For the device center, certain devices are perennial concerns – notably, infusion pumps and automated external defibrillators (AEDs).

"We continue to have problems with infusion pumps," CDRH's Spears said. "We had a public meeting in October looking at infusion pumps and basically trying to get input from industry and others to talk about what the issues are … so they can work on addressing those problems.

"AEDs also continue to be an issue," he noted. "We had a similar meeting with regard to defibrillators in December. So those are two product areas that continue to be of concern."

As for in vitro diagnostics, Gutierrez said OIVD in 2011 will be taking a closer look at troponin tests, glucose meters and blood anticoagulation devices, especially those used in the home.

"We do see a fair amount of MDRs [Medical Device Reports, or adverse event reports] in those areas, and we do keep an eye peeled to make sure that if we're seeing MDRs, we learn what the cause of those MDRs is, and whether there is a need for recalls," he said.

FDA Reaching Out With Recall Information

As for communicating recall information to the public, FDA is working through different social networking channels to ensure that recall messages are widely disseminated.

"We certainly are making efforts to make recall information more readily available to industry and the public," FDA's Zamora said. "We have looked into redesigning our recall page that you can find at www.FDA.gov to make it more consumer-friendly."

Further, the agency has worked with Flickr, an online photo management and sharing application, to post pictures of labels and recalled products.

FDA and CDRH also have pages on Facebook where recall information could be announced. "FDA has reached out and is using social networking sites, and some of those sites may have some association with the recalls that we handle and the products we regulate," Zamora said.

In addition, FDA's recent transparency initiative has had an impact on recall communications, Spears said.

"There is a lot of activity around that initiative to try to get more information to the public quicker. That's what the whole thing is about, and that includes the recall arena," he said. "It helps us identify information we can share with the public right away, and we may go to the company and say, 'You need to do this right away' more actively than before."

Nevertheless, there is still debate within the agency about what information should and should not be released.

FDA considers, "What can we put out early on, and what can't we?" Spears said. "We've had a lot of discussions about that – about how much information we can put out – and then we get into verification of information, too, so we walk a fine line.

"We want to make sure that we put information out quickly to help protect users and patients, and so forth, but we don't want to put out information that is not complete or is alarming if it has not been verified," he added.

Group Looks To Improve Communication

Still, for patients with implanted devices and their physicians, it's not always easy to know when a device has been recalled.

To fill that gap, the nonprofit Biomedical Research and Education Foundation recently developed the Medical Device Registry, an online database where patients can enter information about their implants and be notified if they are recalled.

FDA Can Force Recalls

FDA can put pressure on a manufacturer to conduct a product recall. "It does happen. I can't tell you the frequency or percentage of occurrence, but I will say that we have a lot of conversations with companies in terms of their recall activities and communications. Is the recall notification adequate or not? It's certainly one of the things that we ask ourselves, and often we'll go to the firm to have them change the notification. That's one issue.

"There are also times where a company does not think that it needs to conduct a recall, and it's a matter of them not understanding their obligations as a manufacturer. Often they have a problem, they have a fix that they need to make to a device or a fix that they have already made to the device, and they just want to make the fix and move on. They don't understand what their legal requirements are.

"So some of it is just education, and once they're educated about it, they don't do it anymore. So by and large, companies are cooperative when things like that are brought to their attention. There are some firms that are a little more resistant, but that's going to happen.

"When you look at the range of different kinds of companies that are out there, some of them are pretty experienced with medical device regulation and understand their roles, while others are brand new. They don't really know what they're expected to do. They really are not prepared to be in this world of medical device regulation yet. That's why we have a role in educating them."

– Larry Spears, deputy director of regulatory affairs, CDRH Office of Compliance

The site also offers a searchable list of current device recalls and safety alerts, allowing patients to see if any questions have been raised about a device before agreeing to have it implanted.

Primary care physicians "don't get information at all" about their patients' implanted medical devices, unless a patient remembers to record precise data about the implant and pass it on to his or her doctor, explained Terry Fadem, president of BREF's board of directors.

"So we have a kind of flawed system," he said.

The BREF registry aims to help doctors and patients find out about device recalls or safety alerts.

Both BREF and its device registry – found at www.MedicalDeviceRegistry.org – are supported by funding from philanthropic groups and private donors. According to the organization's website, "BREF's information and research is free of market bias and has no vested or financial interest in any technology reviewed."

In addition, Fadem said BREF made a decision early on not to take money from device manufacturers out of concern that patients would believe that industry was "somehow influencing how the data is collected and reported."

In addition to his role at BREF, Fadem is director of the Office of Corporate Alliances at the University of Pennsylvania School of Medicine. He said he found himself repeatedly fielding questions from primary care physicians whose patients had heard about recalls involving stents, artificial joints and other implants.

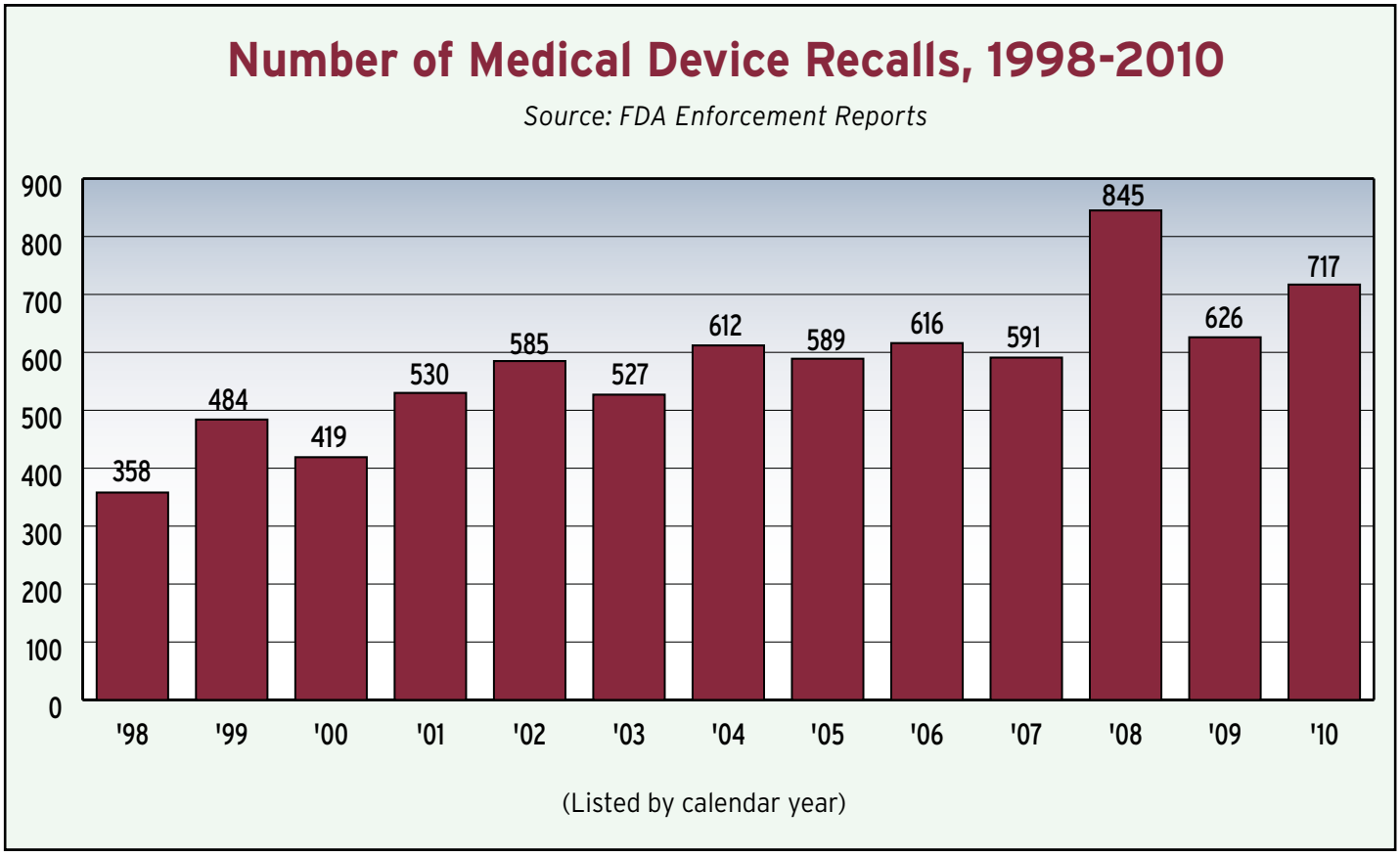
The doctors had no choice but to call several hospitals to track down specific recall information on behalf of their patients.

It's because of that problem that BREF developed its medical device registry as a resource. Patients who register their implants on the site are asked to provide the device's name, manufacturer, device type, product code and lot number, plus information about whether their implant experience was "good," "bad" or "neutral."

In return, the BREF registry automatically forwards to patients FDA information on recalls and other device safety alerts. The registry is open to information on all types of implants.

The site also allows patients to enter detailed complaints about their devices, although those entries will not be viewable to others.

To the extent that the BREF registry allows "patients to register themselves, and then get timely information on the



States Still Waiting On RES

Although FDA promised health and agriculture departments nationwide that they would have access to the agency's Recall Enterprise System (RES) by 2009, FDA is still working on the project.

RES is a database that includes the full array of communications between the agency's district offices and headquarters concerning product recalls.

Information on thousands of recall events involving devices, drugs, biologics, foods and veterinary medicines have been entered into the database since the agency began using the system internally in 2002. ("The Silver Sheet" February 2010).

"We're much closer," said Armando Zamora, leader of FDA's Recall Operations Team. "I can't tell you an exact timeframe because of things that are out of my control when it comes to programming, especially on the IT side, but I can tell you from what I understand of the work that is being done with the Recall Enterprise System and sharing information with the states, I think we are getting closer. We are a lot further along in the process than we were last year."

products they may use or be implanted with, it sounds like a reasonable idea," said Tom Gross, deputy director of CDRH's Office of Surveillance and Biometrics (OSB).

Gross added that while FDA has several avenues to disseminate information about device recalls and problems, most of them rely heavily on manufacturers to alert device users.

This is particularly true for user complaints, which are received and investigated by manufacturers. Those complaints may eventually be submitted for public posting on FDA's Manufacturer and User Device Experience (MAUDE) database.

"What is contained in MAUDE are the adverse event reports that reflect a subset of the complaints received by manufacturers," Gross said.

Although the information found in MAUDE is publicly accessible, Gross said, patients have to be proactive and search the FDA site themselves, as opposed to automatically receiving a report.

In addition, patients have to know the specific model name or product number of the implant they received to make effective use of the MAUDE site.

"There's a way of getting that [information], but by and large, people don't have, or don't remember ... or don't collect that kind of information," Gross said.

CDRH Getting Signals Despite Loss Of Matrix

Last year former CDRH Compliance Director Tim Ulatowski told "The Silver Sheet" that CDRH's matrix team played a "key role in signal identification and signal escalation" with regard to recalls ("The Silver Sheet" February 2010).

The matrix brought together pre-market reviewers, adverse event analysts, scientific researchers and others to evaluate safety risks for different device types ("The Silver Sheet" September 2009).

However, the device center discontinued the matrix last June. Does that mean CDRH lost a key tool for identifying troubling recall trends?

Not necessarily, says FDA's Spears.

"I don't know that I would agree that it was necessarily a 'key signal,'" he said. "The matrix was certainly one source of signal information, but there are many other sources as well. In fact, in many cases the matrix was pulling information from various other sources we already had, such as MDR data, and other data with regard to the performance of product.

"The matrix was getting information and it was evaluating and characterizing the information to help us make better decisions," Spears continued. "It was doing a valuable thing, I believe, but there are many other sources of signal information. I mentioned MDR reports, and the analysis of those reports to judge the impact. We certainly get signals from inspections. We get signals from trade complaints and from other agencies – state, federal and local – and so forth.

"We get signals from a lot of different sources, so I think it's just a matter of looking at things a little bit differently," Spears said. "The matrix served its purpose for awhile. The decision by center management at this point is to say, 'Let's look at something different. Let's look at a different way of capturing that information.' So I don't really see it as a loss, I just think it's just a change in direction."

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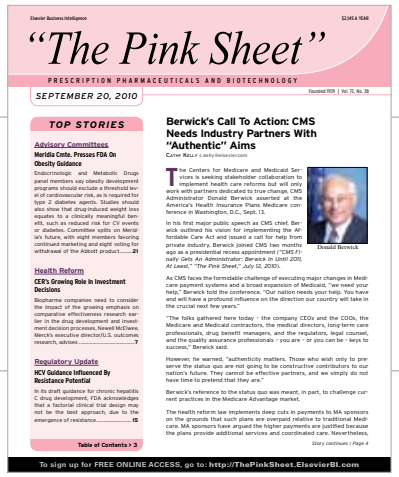

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2010 MEDICAL DEVICE RECALLS

The following list of medical device recalls was compiled by *"The Silver Sheet"* from FDA's weekly *Enforcement Report* issued during calendar year 2010. Entries are listed alphabetically by company. Class I recalls are shaded green.

There can be a delay of weeks or months between a company's recall and its appearance in the *Enforcement Report*. Therefore, some of the recalls on the following list may have taken place prior to 2010, while some recalls that occurred during the year are not included because FDA has not yet published them in an *Enforcement Report*. The list below includes only those recalls pertaining to medical device products; recalls for non-medical device products that are under the jurisdiction of the Center for Devices and Radiological Health, such as laser pointers, tanning beds and airport X-ray systems, have been excluded.

Manufacturer	Product	Class	Reason
3D Machining	Modular Foot System Locking Screw	II	The recalling firm packaged MFT-021-35-24 screws from Lot 0964092 as MFT-021-35-22 Lot 0964081. (Z-1784-2010)
3M	Red Dot Monitoring Electrode	II	The sensing element may have corrosion. In an emergency situation where defibrillation is necessary and electrodes are already in use, the electrodes may malfunction and provide a delayed or no trace response. (Z-2383-2010)
3M	ESPE Stainless Steel Primary Molar Crowns	III	The crown contained within the package is incorrectly labeled. Series UL3 crowns are labeled Series UR3, and vice-versa. The lid of the package correctly identified the product number and lot. This mislabeling could result in placement on the right side of a crown intended for use on the left, and vice-versa. (Z-0463-2011)
3M	***Micropore*** Single-Use Surgical Tape	II	Reduced adhesion of tape. (Z-1413/1420-2010)
3M	***Sendax*** MDI Mini Dental Implant O-Ball Prosthetic Head	II	Product has incorrect size labeling. (Z-1703-2010)
Abaxis	***Piccolo*** Comprehensive Metabolic Panel Reagent Disc	II	Wrong barcode applied to a lot of items, which may result in incorrect calibration factors and results. (Z-1155-2010)
Abbott	***Architect i2000*** and ***Architect i2000 SR*** Wash Buffer and Wash Zone Mechanism Grounding Kit	II	Under certain conditions, the product's wash buffer containing sodium azide can come into contact with the wash zone mechanism ground cables on either of the two wash zones. The copper in the ground strap may corrode and form an unstable chemical substance (metal azide) that may be sensitive to direct pressure and impact. (Z-0132-2010)
Abbott	***Xact*** Carotid Stent System	II	The product was distributed prior to approval of a PMA supplement for a manufacturing line move between sites. There are no product quality issues associated with this action. (Z-1152/1153-2010)
Abbott	Various ***Cell-Dyn*** Hematology Analyzers	II	Epoxy holding the two parts of the waste reservoir together fails, potentially resulting in biohazardous fluid leaks. (Z-2350/2353-2010)
Abbott	***Cell-Dyn Sapphire*** Probe Detector PCB Assembly	II	Under certain conditions in closed mode of operations, the aspiration probe detector PCB assembly may fail to operate properly and provide inaccurate results. (Z-2421-2010)
Abbott	Clinical Chemistry Phosphorus Assay	II	Product may give inaccurate results and aspiration errors with reagent configuration, including results outside of linear range and calibration failure. (Z-2398-2010)
Abbott	***GCX*** Mountable Downloader-Recharger	III	Reliability issues associated with broken connection pins within the downloader that mate with the pins from the analyzer. (Z-2462-201)
Abbott	***Cell-Dyn*** Vent Needle	II	Needle may be defective, which may result in an undetected short sample, generating incorrect low results, or may bend, preventing aspiration of the sample. (Z-0489-2011)

Manufacturer	Product	Class	Reason
Abbott	***i-STAT ACT*** Cartridges	II	Cartridges may be difficult to fill or will not fill when attempting to transfer blood to the sample entry port of the cartridge. (Z-0399/0400-2011)
Abbott	Paraffin Pretreatment Reagent Kits II and III	II	The kits do not have any hazardous or MSDS information included in their labeling. (Z-1147/1148-2010)
Abbott	***i-STAT 1*** Analyzer	II	The storage temperature on the label on the side of the shipping box does not match product specification. (Z-0812-2010)
Abbott	***i-STAT*** PT/INR Cartridge	II	A high mean bias was documented in eight lots of cartridges. This may lead a clinician to believe that a patient is adequately anticoagulated when they are not. Inadequate anticoagluation therapy may be given and issues with clotting and/or thrombosis could occur. (Z-1996-2010)
Abbott	***Martel*** Printer	II	Some printers used with the ***i-STAT 1*** system have the potential of being damaged due to the use of rechargeable battery packs that do not contain a fuse. (Z-1133-2010)
Abbott	Various ***i-STAT*** Cartridges	II	There is a dependence of the ***i-STAT*** Hct assay on the vertical pitch angle of the ***i-STAT*** analyzer during the blood analysis cycle. (Z-1791/1798-2010)
Abbott	***Rx Acculink*** Carotid Stent System	II	The affected lot may not meet quality specifications for catheter shaft tensile strength. (Z-0749-2010)
Accellent	***EndoClamp*** Aortic Catheter	I	Spontaneous balloon rupture during use of the product. (Z-0084/0085-2010)
Ace Surgical Supply	Calcium Sulfate Hemihydrate Kits	II	***Fast Set*** potassium sulfate solution may not be sterile. (Z-1805/1806-2010)
Acumed	***Polarus*** Humeral Fixation System	II	Product labeled "cortical bone screw" actually contains an ***Acutract*** fixation screw. (Z-1602-2010)
Acumed	Intramedullary Fixation Rod	II	Products improperly handled after cleaning, prior to sanitation, and may be contaminated with inorganic material. (Z-1552-2010)
A-Dec	***Decade Plus*** Dental Chair	II	The design of the chair backrest creates a possible pinch-point between the chair backrest and the underside of the armrests. (Z-0541-2011)
Advanced Input Devices	***Symbia*** SPECT Systems	II	Some of the system hand controllers are missing a resistor switch, and the absence of the switch may lead to unintended system motion during camera setup activities. (Z-0583/0584-2010)
Advanced Medical Optics	***Complete*** Multi-Purpose Solution; ***Total Care*** Contact Lens Solution	II	The flip-top caps used during production of these solutions may leak and, although unlikely, the sterility of the product may be compromised. Products that are non-sterile have the potential to cause eye infections, which may be sight-threatening. (Z-0129/0130-2011)
Advanced Neuromodulation	***Eon*** Mini Implantable Pulse Generator	II	Devices may experience a gradual or sudden loss of charging capability. (Z-1599-2010)
Advanced Neuromodulation	***Swift-Lock*** Anchor Accessory Kit	II	Directions for use of product incorrectly stated lead compatibility information. (Z-1425-2010)
Advanced Orthopaedic Solutions	Trochanteric Nail	II	One piece of the nail was incorrectly bent. (Z-1181/1192-2010)

Manufacturer	Product	Class	Reason
AdvanDx	*E.faecalis*/OE PNA FISH	II	Some strains of *streptococcus anginosus* cross-reach with *E. faecalis*/OE PNA FISH to produce a false-positive green signal. (Z-2315-2010)
AdvanDx	EK/*P. aeruginosa* PNA FISH Culture Identification Kit	II	Strains of *Acinetobacter radioresistens* cross-react with both *E. coli*/*P. aeruginosa* PNA FISH and EK /*P. aeruginosa* PNA FISH to produce a false-positive red signal. (Z-0491-2011)
Agendia	***MammaPrint*** Breast Cancer Recurrence Assay	II	The ***MammaPrint*** test has been over-reporting the chance of metastasis risk being 29% risk of recurrence instead of 10% risk. This over-reporting of risk did not cause direct injury to patients. However, if used by physicians as the sole basis for decision-making, affected patients may have received unnecessary therapy. (Z-1321-2010)
AGFA	***Impax CV*** Results Manager/Results Manager Administration Tool	II	AGFA service technician incorrectly modified a report template at one site, resulting in erroneous anatomic segment locators. (Z-2112-2010)
AGFA	***DT2 Mammo***	III	The RF tags on the white protection sheets of the media stacks were incorrect. (Z-1799-2010)
Air Optix	***PT Ciba Vision***	II	The lenses inside the package do not match the prescription information for power labeled on the primary package. (Z-17062010)
Alcon	Various ***Constellation*** Vision Systems	II	System performance and machine settings may impact the infusion performance. (Z-1924/1934-2010)
Allergan	***Lap-Band*** Adjustable Gastric Band System	II	Ports were damaged by the insertion of needles into the septum of the port at an oblique angle. (Z-0418-2011)
American Diagnostica	Imubind Plasma PAI-1 Elisa	II	Unacceptable microwell-to-microwell variation in the section of the plate that is typically used for the calibrators. (Z-1426-2010)
Amifactirer Inion	***Inion*** CPS Baby Screw	II	Screws did not meet shear and torsion testing specifications. (Z-1550-2010)
AMO Manufacturing	***Tecnis*** Intraocular Lens	II	Some lenses have adhered to the optic lens after insertion into the eye. This can lead to a need for additional manipulation to separate the haptics from the optic during surgery, which could lead to an injury. (Z-0605-2010)
Amori Olympus	***Olympus SD*** Snares	II	An investigation of consumer complaints revealed the inability of the snare wire to be retracted into the snare tube after deployment of the snare. (Z-2236-2010)
AMS Innovative Center	***GreenLight HPS*** Fiber Optics	II	Product may be packed with incorrect external or internal labels, and/or missing product insert. (Z-2502-2010)
Andreas Hettich	Various ***Mikro*** and ***Haematokrit*** Centrifuges	I	The centrifuge rotor may crack, break and explode outside of the centrifuge. (Z-0612/0615-2010)
AngioDynamics	***Duramax*** Hemodialysis Catheters	II	The product has the potential for a cross-lumen leak. (Z-1761/1771-2010)
AngioDynamics	***Benephit XT*** Infusion System	II	***Benephit*** infusion catheters may exhibit a hole or tear in the primary sterile barrier packaging. (Z-1733/1734)2010.
AngioDynamics	***PulseSpray*** Infusion System	II	A particular lot was packaged with the wrong occluding ball guide wire. (Z-1707-2010)
AngioScore	***AngioSculpt*** Percutaneous Transluminal Coronary Angioplasty Catheter	I	Separations of the catheter shaft at the guide wire exit port have occurred during treatment of coronary artery stenosis. Fragments of the catheter may become lodged in coronary arteries, resulting in serious patient outcomes, requiring emergency coronary bypass surgery and medical intervention to remove the retained device fragments. (Z-2218-2010)

Manufacturer	Product	Class	Reason
Angiotech	***Xia Precision*** System	II	Packaging failures during shipping. (Z-0789/0792-2010)
Animas	***OneTouch Ping*** Insulin Pump	III	Software malfunction, which does not allow users to download, view and print information from their pump (including blood glucose, insulin delivery, carbohydrate and pump events). Additionally, users are unable to customize the built-in food database and pump settings using the software. (Z-1560-2010)
Argon Medical Devices	Percutaneous Catheter Introducer Set	III	One lot contained an incorrectly sized needle. (Z-0764-2010)
Argon Medical Devices	Arterial Line Kit; Catheter Introducer Kit PCI Kit; Catheter Introducer Kit Special Right Heart Kit	II	There are one or two places on some of the kit blister trays where there are holes and/or the material is so thin that holes are easily created. This would potentially cause the sterility of the products to be compromised. (Z-1737/1745-2010)
Argon Medical Devices	***Aquatrack*** Hydrophilic Nitinol Guide Wire	II	Some of the guide wires have a straight tip rather than an angled tip. (Z-0623-2010)
Arizant	AC Power Cords	II	Customer reports of melting, smoking or fire within the power-cord plug. The potential risks from this power-cord failure include electric shock, delay in setup and therapy, interruption of therapy, device failure and fires. (Z-0895/0898-2010)
Arrow International	Percutaneous Sheath Introducer Kit with Integral Hemostasis Valve/ Side Port	II	Some central venous catheter sets had the incorrect lid stock. (Z-1538-2010)
Arrow International	***MAC*** Two Lumen Central Venous Access Kit; Percutaneous Sheath Introducer Kit; Multi-Lumen Central Venous Catheterization Kit; Two-Lumen Central Venous Catheterization Kit	I	***Q-Syte*** component contained in kits was recalled by manufacturer due to the potential for embolism if used with a central venous catheter. (Z-0783/0788)2010.
Arrow International	Arrow Peripherally Inserted Central Catheter Kits	II	Arrow has received complaints of the PICC catheter fitting too tightly in the "kit-supplied" peelable sheath. In some cases, clinicians have been unable to insert the catheter through the peelable sheath during the insertion procedure. If the catheter will not pass through the sheath, the clinician is required to place a guide wire back into the sheath, remove the sheath, and place another sheath that the catheter will pass through. This may delay the procedure and/or increase the need for a repeat procedure. Risks associated with delay and/or repeat procedure may include bleeding and infection. (Z-1682-2010)
Arrow International	Percutaneous Sheath Introducer Kit	II	The stopcock handle position was inadvertently changed from an open to a closed position, which prevents sterilization of the closed portion of the device. Sterility of the affected product cannot be guaranteed. (Z-2274-2010)
Arrow International	Various Central Venous Catheterization Kits; Arterial Catheterization Set; Femoral Artery Catheterization Set	II	Incorrectly assembled introducer needle. (Z-2489/2496-2010)
Arrow International	Intravenous Administration Sets and Accessories	I	Sterility may be compromised. (Z-1112/1130-2010)

Manufacturer	Product	Class	Reason
Arrow International	AVI Sterile Impad Rigid Sole Foot Cover	II	120 cases of each Lot Code 6066 (right foot) and 6067 (left foot) were shipped to the distributor before sterilization. (Z-2656/2657-2010)
Ascension Orthopedics	***PyroCarbon*** PIP Total Joint	II	Trial product was larger than actual implant. Trial product was re-designed to more closely match the implant. (Z-1524-2010)
Ascension Orthopedics	***PyroHemiSphere*** (aka ***NuGrip***)	II	Two different product lots were found to be incorrectly labeled and placed into the incorrect box. (Z-0437/0438-2011)
Ascent Healthcare Solutions	***FemoStop*** Devices	II	Devices may fail to inflate or hold pressure. A separation between the dome and arch base prevents the device from maintaining pressure when inflated. (Z-2196-2010)
Atek Medical Manufacturing	***Octopus Nuvo*** Tissue Stabilizer	I	The collet may fracture, causing immediate separation of the head link from the shaft of the device. The resulting potential hazards are that fragments of the collet could fall into the patient's chest cavity and/or damage the heart tissue. (Z-0134-2011)
Atrium Medical	***HydraGlide*** Silicone Chest Tube Catheter	II	One lot of straight catheters incorrectly packaged and labeled as "24 Fr. Straight Catheters." (Z-0019/0020-2011)
Availmed	***Exacta-Mix*** EVA Container; ***Halobag*** EVA Dual-Chamber Bag; ***Exacta-Mix*** Calibration Bag; ***Exacta-Mix 2400*** Valve Assembly with Calibration Bag; ***Exacta-Mix*** Valve Set	II	Fill port cap on TPN bags may become detached prior to use, compromising the sterility of the fluid pathway. (Z-2137/2148-2010)
Availmed	***Everest*** Disposable Inflation Devices	II	Product sterility may be compromised due to breach of package seal integrity. (Z-2271/2273-2010)
Axis-Shield Diagnostics	***IMx Sirolimus*** Reagent Pack	II	Reagent exhibited an increased frequency of calibration errors. (Z-2171-2010)
B. Braun	***addEASE*** Binary Connector	I	During this insertion, fragmentation of the PAB container stopper may occur, resulting in a small amount of visible particulates in the solution. (Z-0305/0306-2011)
B. Braun	***Outlook*** Pump I.V. Set	II	A "System Error 9" alarm indicates a potential pressure loss in the pump cassette delivery chamber. This alarm is generated during the pump's initiation sequence and will not allow the set to be utilized. This requires a new set to be obtained, thus creating a potential for delay in therapy. (Z-0670/0718-2010)
Bard	***PowerPort*** isp M.R.I Implanted Port	II	8 Fr. ***PowerPort*** stems were mixed with 6 Fr. PowerPort devices and packaged. (Z-1525-2010)
Bard	***Huber Plus*** Non-Coring Needle Safety Infusion Set	II	After activation of the safety mechanism, the tip of the needle protrudes from the safety sheath, creating the potential for needlestick injury. (Z-0861/0862-2010)
Bard	***Dorado*** PTA Balloon Dilatation Catheters	II	Catheters contain materials that, under certain conditions, are subject to premature breakage, allowing the balloon to partially or completely separate from the catheter shaft. (Z-2122/2136-2010)
Bard	***Magnum*** Disposable Biopsy Core Needle	II	Needle may exhibit an exposed sample chamber due to extended stylet length resulting from a loose hub connection. The exposed sample chamber will typically result in an inability to obtain the biopsy sample. When used in highly vascular organs, the exposed sample chamber may, in rare instances, result in trauma or puncture to neighboring tissue and lead to subsequent bleeding. (Z-0273/0276-2010)

Manufacturer	Product	Class	Reason
Bard	Mesh Pre-Shaped	II	Product was mislabeled. (Z-0446-2011)
Bard	Various ***Ventrio*** Hernia Patches	II	Hernia patch may be a different size than noted on the product label. (Z-0422/0424-2011)
Barnant	***CircuCool*** Fluid Circulation Pump	II	Product may cease operation as a result of potential speed control board failure when the device is shut off, and may not turn back on. A component on the circuit board fails unexpectedly because of a power surge, causing a diode to burn out. (Z-1156-2010)
Bausch & Lomb	Various Types/Models of Phaco Pack with Needles	II	Users may incorrectly assemble the plastic needle wrench to the phacoemulsification needle, resulting in the generation of plastic particulate. (Z-1708/1730-2010)
Bausch & Lomb	***Millennium*** Microsurgical System; ***Stellaris*** Vision Enhancement System	II	The AC power cords used on these products are subject to an FDA alert. (Z-1662/1664-2010)
Bausch & Lomb	***Boston ES*** Rigid Gas Permeable Contact Lens	II	The amount of D&C No. 6 dye added to the formulation exceeded specified amounts. (Z-1705-2010)
Bausch & Lomb	***Boston*** Conditioning Solution	II	The product failed to meet out-of-specification shelf life at the nine-month time point. (Z-0553-2010)
Bausch & Lomb	***SoFlex SE*** Foldable Intraocular Lens	II	Opacification of the intraocular lens. The opacification occurred within one week of implantation. In each reported case the surgeon explanted the lens. (Z-0591-2010)
Baxa	***Exacta Mix*** Total Parenteral Nutrition Bag	II	Bags may leak fluid due to inadequate sealing. (Z-1030/1032-2010)
Baxter	Various Extension and Infusion Sets	II	Baxter observed tears and pinholes in chevron-style pouches for certain infusion-disposable products. The pinholes and tears could compromise the sterile barrier properties of the pouch. (Z-0148/0158-2011)
Baxter	***HomeChoice*** and ***HomeChoice Pro*** Automated Peritoneal Dialysis Systems	I	Potential overfill of the peritoneal cavity, also referred to as increased intraperitoneal volume (IIPV). IIPV can result in serious injury or death. (Z-0799/0800-2010)
Baxter	***RenAmin*** (Amino Acid) Injection; Evacuated Container	II	Routine stability testing of the evacuated container product, along with trending of results, indicates that the pH will exceed the upper specification limit prior to the expiration date of this product. (Z-1528/1530-2010)
Baxter	***Coseal*** Surgical Sealant	II	Out-of-specification results at the 18-month and 21-month time points for the percent thiol substitution. The parameter that is out-of-specification is an indicator of possible failure for the product to gel appropriately. (Z-1948/1950-2010)
Baxter	***Interlink*** System Buretrol Solution Set	II	There are leaks in the drip chamber check value subassembly of the solution set. A leak in a sterile pathway could allow microbial entry, which could lead to a bloodstream infection. (Z-0070-2011)
Baxter	1550 Single Patient System Hemodialysis Machines	II	Some of the hemodialysis instruments may have replacement circuit boards with incorrect versions of software. (Z-1322-2010)
Baxter	***Colleague*** Single-and Triple-Channel Volumetric Infusion Pumps	I	The FDA sent a letter to Baxter on April 30, 2010, ordering the company to recall and destroy all models of its ***Colleague*** volumetric infusion pumps currently in use in the United States. FDA determined that this action was necessary because Baxter failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague pumps still in use. (Z-0001/0002-2011)

Manufacturer	Product	Class	Reason
Baxter	Three-Way Large Bore Stopcock with Rotating Male Luer Lock Adapter and Male Luer Slip	II	Rotating the handle on the stopcock past the stop can cause the stopcock to leak. A leak can lead to under-infusion or interruption of critical life-sustaining therapy. (Z-0586/0587-2011)
Baxter	***Buretrol*** Solution Sets	II	The tubing may separate from the distal site of the set, which could result in patient injury if the separation occurs during patient use. (Z-0487-2010)
Baylis Medical	***LumbarCool*** Pain Management Kit	II	Name of the device reflected on the product packing sleeve is incorrect. (Z-1755-2010)
BD	FACS Sample Prep Assistant III	II	Due to inaccurate sample dispense, use of product may result in getting incorrect results on samples prepared using the device. (Z-0316-2011)
BD	***FACSCount*** Controls Kit	III	The product is mislabeled. (Z-1007-2010)
BD	FACS Sample Prep Assistant II	II	Samples produced inaccurate sample results due to inaccurate sample dispensed as a result of the cap-piercing probe. (Z-1940-2010)
BD	***GeneOhm*** C. Diff Assay	II	In vitro diagnostic test kits do not perform to specifications. (Z-2174-2010)
BD	Syringes	II	Reports received of open seals. (Z-0586-2010)
BD	***Difco*** Decarboxylase Base Moeller	III	Diagnostic test reagents may not meet quality control specifications. (Z-1787-2010)
BD	***Difco*** *Salmonella* O Group A Antigen	III	In vitro diagnostic reagent may exhibit decreased or no reactivity. (Z-2025-2010)
BD	***PrecisionGlide*** Needle	II	Reports of blocked/clogged needles. (Z-0023-2011)
BD	***Beaver Arthro-Lok*** Pointed Tip Blade	II	Blade curves right instead of left. (Z-1638-2010)
BD	***Q-Syte*** Split-Septum, Extension Set, and Vial Access Adapter; ***MPS Acacia*** Extension Sets	I	Manufacturing defect may allow air entry into a central venous catheter, possibly resulting in an air embolism. (Z-0750/0756-2010)
BD	***Q-Syte*** Split-Septum, Extension Set, and Vial Access Adapter; ***MPS Acacia*** Extension Sets; ***Nexiva*** Catheter Systems	I	Manufacturing defect may allow air entry into a central venous catheter, possibly resulting in an air embolism. (Z-0752/0840-2010)
BD	I.V. Start Bundle Kit; Venous Access Tray; Dialysis Kit	I	Manufacturing defect may allow air entry into a central venous catheter, possibly resulting in an air embolism. (Z-1073/1075-2010)
BD	***Probetec ET*** CT/GC Endocervical Specimen Collection and Dry Transport System – Pink Cap	II	Product was shipped beyond its expiration date. (Z-0969-2010)
BD	***Visitec EdgeAhead*** MVR Knife	III	Labeling mix-up. (Z-1597-2010)
Beckman Coulter	***LH*** and ***GEN*S SlideMakers***	II	The sample ID information embedded in the barcode affixed to a slide made by the ***GEN*S*** and ***LH SlideMakers*** does not match the text. (Z-0850/0851-2010)
Beckman Coulter	***UniCel*** Immunoassay and Clinical Systems	II	Premature failure of the upper aspirate peristaltic pump. (Z-0914-2010)
Beckman Coulter	***UniCel DxC Synchron*** Clinical Systems	I	Excessive buildup of protein, bacteria and sample tube additives in the ISE flow cell may cause erroneous NA (sodium) results. (Z-0863-2010)

Manufacturer	Product	Class	Reason
Beckman Coulter	***Access*** Immunoassay Systems Reagent Kit	II	Different results have been obtained using the same patient samples on ***Access/Access 2*** and ***UniCel DxI*** platforms. Values obtained with UniCel DxI systems have been demonstrated to have a positive bias compared to values obtained with Access or Access 2 systems. (Z-1318-2010)
Beckman Coulter	***UniCel DxH 800*** Cellular Analysis System	II	Problems related to host transmissions. This information only affects instruments interfaced to a host system. (Z-1680-2010)
Beckman Coulter	***LH 500*** Series System; ***Unicel DxH 800*** Cellular Analysis System	III	The system will substitute or omit the characters # @ [\] ' {|} when the system is configured in a language other than English or Chinese. The system will also omit the character ~ regardless of language, leaving a potential for specimen or patient misidentification. (Z-1657/1658-2010)
Beckman Coulter	***PrepPlus***; ***PrepPlus 2***	II	Dilution of reagent vials loaded onto the ***PrepPlus*** or ***PrepPlus 2*** systems. This problem could result in dilution of affected antibody vials, which may diminish cellular fluorescence staining and present a risk of erroneously low results. (Z-1758/1759-2010)
Beckman Coulter	***Unicel DxH 800*** Cellular Analysis System	II	There is a potential for a false increase in platelet results due to micro-bubbles. This situation could present a risk of falsely increased platelet results in patient samples as diluent containers are depleted. (Z-1905-2010)
Beckman Coulter	***Access*** Immunoassay Systems AFP QC	III	Vials of QC1 in the kits contain microbial contamination. Elevated CVs may also be observed with the contaminated vials. (Z-2208-2010)
Beckman Coulter	***Access*** Thyroglobulin Antibody II Reagent	II	Reagent may produce inaccurate results due to a change in the thyroglobulin that was used in the kits. (Z-2355-2010)
Beckman Coulter	***LH500*** Series System; ***Unicel DxH800*** Cellular Analysis System	III	Beckman Coulter identified four issues with systems. Issue 1: There is a potential for misidentification to occur when the system is configured in languages other than English or Chinese. The characters #, @, [, \,], ', {, |, } or ~ are substituted or omitted in other languages. Issue 2: Independent of language, the ***DxH800*** omits the characters *?" when used as part of the selected demographics including Specimen ID and Patient ID. Issue 3: In the DxH 800, space(s) used as leading character(s) in a Patient ID or Specimen ID can cause random insertion of extra character(s) within that identifier. Issue 4: The ***LH500*** instrument omits the tilde character (~) from the barcode when read by the primary mode (automatic aspiration) scanner. This is independent of language configuration on the system. (Z-2337/2338-2010)
Beckman Coulter	***UniCel DxC*** and ***Synchron LX*** Instruments	II	Instruments produced inaccurate (low) GLUCm results. False-low results could affect or delay diagnosis or treatment. (Z-2388-2010)
Beckman Coulter	***Access*** Immunoassay Systems Free T4 Reagent	II	Kit boxes may contain reagent packs labeled as "***Access*** Vitamin B12." Using an Access Vitamin B12 reagent pack filled with Access Free T4 reagents may generate incorrect patient results. (Z-2658-2010)
Beckman Coulter	***Immage*** Immunochemistry Systems Buffer 1 (BUF1)	II	Some lots have been reported to cause high shifts in recovery of control or patient samples. Quality control failures may result after replacing BUF1 with a different lot. (Z-2195-2010)
Beckman Coulter	***Synchron*** Gentamicin Reagent	II	The reagent produces false-low test results. A false-low result can cause a patient to receive more medication than necessary. (Z-2437-2010)

Manufacturer	Product	Class	Reason
Beckman Coulter	***Unicel Synchron*** Clinical Systems Closed Tube Aliquotter	II	A loose aliquot probe tube fits in the closed tube aliquotter. This may result in dilution of the sample with wash buffer; patient results can potentially be affected for ***Access*** immunoassays or ***Synchron*** chemistries. Access quality control may also be affected if run through the CTA. (Z-2441/2442-2010)
Beckman Coulter	***Access*** Immunoassay Systems Progesterone and Cortisol	II	Reagent may produce suppressed patient results. Further, the reagent may produce suppressed patient results and an increased incidence of IND flags. (Z-2620/2621-2010)
Beckman Coulter	***Synchron*** System Immunoglobulin A Reagent	II	Reports of high recovery of immunoglobulin A (Ig-A) in proficiency surveys or patient samples using ***Synchron*** reagent. (Z-2653-2010)
Beckman Coulter	Various ***UniCel DxC*** Systems	II	Product may exhibit issues with stat sample-rack loading, causing a possible delay in results. (Z-2590-2010)
Beckman Coulter	Active I-PTH Enzyme-Linked Immunosorbent Assay (ELISA)	II	ELISA kits may produce falsely elevated patient results. (Z-0107-2011)
Beckman Coulter	***Access*** Immunoassay Systems Estradiol	II	Reagent contains an incorrect raw material, which may produce incorrect patient results. (Z-0448-2011)
Beckman Coulter	Sex Hormone Binding Globulin (SHBG) Reagent	II	Instructions for use do not specify the units of measure to be used when calculating the Free Androgen Index. (Z-0431-2011)
Beckman Coulter	***UniCel DxH 800*** Cellular Analysis System	II	The diagnostic procedure is not functioning properly. There is a potential for inadequate sample preparation of samples following the use of this function. Also, use of the "Auto Prune" function causes the deletion of quality control files. If the last run for a control lot is older than the number of days set in Auto Prune (default: 30 days), all of the QC runs of that control file will be deleted. (Z-1656-2010)
Beckman Coulter	***UniCel DxI 800*** and ***600*** Access Immunoassay Systems	II	A software issue was identified, which may result in the incorrect handling of a wash arm dispense plate motion failure. Instead of generating a red warning event and stopping sample processing, the system will post a yellow caution event and continue to operate with the dispense plate in an elevated position until the instrument is re-initialized. Potentially affected results are not flagged. (Z-0856-2010)
Benchmark Electronics	System Components for ***Freestyle Navigator*** Continuous Glucose Monitor System	II	The device's plastic housing near the battery compartment may crack and allow moisture to enter. (Z-0820/1461-2010)
Binding Site	***Bindazyme*** Human C1Q Binding Circulating Immune Complex EIA Kit	III	The kits may contain an ELISA plate labeled as "tissue transglutaminase coated wells" instead of "C1q coated wells." (Z-1942-2010)
Bio Diagnostics	***Biokit*** HSV-2 Rapid Test	II	Negative serum was giving a positive result for herpes simplex type 2 (HSV-2). It is possible that a misdiagnosis (i.e., positive) could be made. (Z-1970/1971-2010)
BioCheck	Human Cardiac Specific Fatty Acid-Binding Protein (H-FABP) Elisa Test Kit	II	Products were marketed without 510(k) for diagnostic use. (Z-2243-2010)
BioHorizons	***Single-Stage*** Healing Abutment	II	Healing abutment may not fully seat on the implant. (Z-0321-2011)
bioMérieux	***Vitek 2***	II	Foil pouch was punctured by drug susceptibility cards during packaging, allowing moisture into pouch, resulting in inaccurate and/or incorrect drug susceptibility results. (Z-2295-2010)

Manufacturer	Product	Class	Reason
bioMérieux	***Vitek 2*** Gram Negative Susceptibility Card	I	The piperacillin/tazobactam drug on the antimicrobial susceptibility cards is providing false susceptibility and false resistance results for *E. coli*; the same drug is providing false susceptibility results for *Klebsiella.* (Z-0172/0285-20110)
Biomet	Bone Mulch Screw	II	The screw may not have the hex dimension inside of the head of the screw, which will prevent the device from being implantable. This may cause a delay in the procedure while another screw is obtained. (Z-0779-2010)
Biomet	***Mallory*** Head Calcar Provisional and Femoral	II	***Mallory*** Head Revision Stems had flute geometry that was out-of-specification. The flute geometry was too deep. (Z-1665/1679-2010)
Biomet	***Ziploop*** Artificial Ligament Fixation Device and Technology Implant Kit	II	The saddle is too long. (Z-1952/1953-2010)
Biomet	Disposable Coring Trephine; Disposable Dowel Harvest Tube; Disposable Coring Trephine	II	The affected instruments are discolored and/or have a sticky residue on the end. (Z-2597/2605-2010)
Biomet	Modular Microplasty Cup Inserter and Impactor Thread Insert	II	There was a clerical error in order entry which resulted in the firm receiving spring components from a supplier made of "music wire." The recalling firm conducted tests to determine the effects of the change in materials. The testing showed that the wire would oxidize and there would be early failure of the device. (Z-2504/2505-2010)
Biomet	Closed Knot Pusher	II	The closed knot pusher is missing a radius, which contributes to sutures being cut during surgery. (Z-0059-2011)
Biomet	Hole Long Plate (Titanium Plate)	II	Mislabeled size. (Z-0108-2011)
Biomet	HT SD X-Drive Screw	III	Product may contain wrong screw. (Z-1943-2010)
Biomet	***Locator*** Restorative Abutment	II	Package labeled as sterile may have an incomplete or partial seal, thereby possibly compromising sterility. (Z-0810-2010)
Biomet	***GS300*** Gold Slotted Screw	II	Product was manufactured with a material not specified for use in this product. (Z-1956-2010)
Biomet	***Micromax L-15*** Suture Anchor	II	The anchor label states that it contains a flexible shaft, but this lot actually contains a rigid shaft. (Z-0611-2010)
Biomet	Byrd Screw	II	The parts were not hardened in the final processing, which led to weaker-than-acceptable material. (Z-0169-2010)
Biomet	Patient Distractor Driver	II	The patient distractor driver, used in osteotomy procedures, may not ratchet and advance the distraction device as intended. If the distraction device does not advance, bone consolidation may occur and a second surgery may be necessary. (Z-1319-2010)
Biomet	***Microfixation*** System High Torque Cross-Drive Screw	III	Wrong screw length. (Z-2206-2010)
Biomet	***Lactosorb*** System Adjustable Self-Drilling Taps	II	The two lots identified have a new-style stop and an old-style tap; they are not compatible because the depth etchings do not line up correctly. Depending on the tap, a person may drill too shallow or too deep. (Z-0489/0490-2010)
Biomet	***Peek Allthread*** Knotless Anchor	II	Anchors may be difficult to remove or may not detach from the inserter shaft. (Z-0191-2010)

Manufacturer	Product	Class	Reason
Bio-Rad	Various Test Cartridges	II	Inaccurate results with high bias. Inaccurate results may be read by the machine, creating the risk for untreated hypoglycemia at elevated altitudes. (Z-0122-2011)
Bio-Rad	***Variant II*** Hemoglobin Testing Systems	II	Sample test results for the first run appear to be correct, but all subsequent results during that run were assigned an incorrect barcode and tube position. (Z-1901/1902-2010)
Bio-Rad	***Monolisa*** Anti-HBs EIA Test Kit	III	The package insert provided with this kit contains a typographical error, giving incorrect directions to prepare a working conjugate solution. If these directions are followed, it would result in a 1:6 dilution and invalidate the assay. (Z-1620-2010)
Bio-Rad	Autoimmune EIA ANA Screening Test Kit	II	The kit generates a high percentage of false-positive results, associated with a low-check-control reading. (Z-0539/0540-2011)
Bio-Rad	Various ***in2it*** Test Cartridges	II	Test cartridges may leak and have the potential to generate error messages and biased inaccurate results. (Z-0109-2011)
Bio-Rad	***Variant II Turbo*** Hemoglobin A1c Program	II	Updated kit CD-ROM will not upload. As a result, the device cannot be run. (Z-0867-2010)
Bio-Rad	Autoimmune EIA Anti-Cardiolipin IgM Test Kit	III	Microbial contamination in positive controls. (Z-1145-2010)
Biosite	***Triage*** Total Controls	II	Incidence of low-recovery results has exceeded post-market surveillance thresholds of customer complaints in the field. (Z-1788/1790-2010)
Biosite	Various ***Cholestech LDX*** Controls and Calibration Verification	II	Results were reported as being out-of-range. (Z-0439/0443-2011)
Bio-Technology General	***Euflexxa***	III	Out-of-specification results for molecular weight or viscosity through the established expiration date. (Z-1635-2010)
Blease	***BleaseSirius*** Anaesthesia System	II	Potential for the touch-screen on the ventilator portion of the device to go blank when touched. This failure may also cause mechanical ventilation to stop. (Z-2113-2010)
Boehringer Wound Systems	***Engenex*** Non-Acute-Care Suction Cup	II	Reduced vacuum capacity has been reported with a small number of units caused by electrostatic discharge or static electricity. (Z-2609-2010)
Boston Scientific	Back-Up ***Meier*** Steerable Guide Wires	II	The polytetrafluoroethylene (PTFE) coating on the gold-plated distal coil of the guide wires has the potential for PTFE delamination. Inconsistent adherence of PTFE coating to this coil portion of the guide wire may cause the PTFE coating to flake or fall off from delamination. Injury to the brain, kidneys and other organs could potentially be caused if the PTFE coating flakes or falls off the guide wire and if PTFE particulates are released into the blood stream. In the most severe cases, injuries could include stroke, irreversible impairment to brain or renal function, blue-toe syndrome and/or other ischemic effects. (Z-1760-2010)
Boston Scientific	***Radial Jaw 4*** Large Capacity with Needle Biopsy Forceps	II	Clevis may detach from the coil, preventing the device to open and/or close. Delays in the procedure may result. (Z-1772/1774-2010)
Boston Scientific	***Ultraflex*** Tracheobronchial and Esophageal Stent Systems	II	There are suture-related device failures during deployment and repositioning of the stent. (Z-1817/1873-2010)
Boston Scientific	***Flexima*** Biliary Stent System	II	Devices were packaged with Tyvek tray lids that had incorrect adhesive, resulting in sterile barrier seal defects. The breach of the sterility barrier could lead to the devices being non-sterile. (Z-1975/1994-2010)

Manufacturer	Product	Class	Reason
Boston Scientific	***Liberté Monorail*** and ***Over-the-Wire*** Coronary Stent Systems	II	***Liberté*** Paclitaxel-Eluting coronary stents have been inadvertently selected when the interventional cardiologist intended to implant a Liberté Bare-Metal stent, and vice-versa. Selecting the wrong device may present a risk of serious injury, including death. (Z-0068-2010)
Boston Scientific	Various ***Ultraflex*** Stent Systems	II	Units have excessive fraying of the deployment suture thread; as a result, these devices may experience a suture break during deployment. (Z-2316/2331-2010)
Boston Scientific	***Bionic Navigator*** Clinician Programmer	II	Sony battery packs installed in Toshiba portable computers can overheat, posing a fire hazard to customers. (Z-1409-2010)
C.R. Bard	Rectal Tubes	III	The product is misbranded. (Z-0465-2011)
Cambridge Heart	***Alternans*** Sensor Kit Assembly	II	Some kits contained a component with an expiration date prior to the date of expiry on the outside of the kit. (Z-1776-2010)
Capintec	***Captus 3000*** Thyroid Uptake System	II	The spring arm on the portable stand may have been over-tightened during assembly, which may result in failure. If the spring arm fails, it will not balance the collimator weight and the arm will drop to the lowest position. (Z-0167-2011)
Cardiac Science	***Powerheart*** and ***CardioVive*** Automated External Defibrillators	I	Certain models may not have received adequate electrical safety testing prior to being shipped from the factory. (Z-1424-2010)
Cardiac Science	***Powerheart***, ***Responder*** and ***CardioVive*** Automated External Defibrillators	I	A component of the device may fail during a rescue attempt and will not be able to deliver therapy. (Z-1243/1249-2010)
Cardiac Science	***Responder 2000*** Defibrillator and Monitor	II	The operator's manual may not have adequate information to clearly explain device behaviors. Pressing and holding down the "Charge" or "Shock" buttons on the ***Responder 2000*** for more than five seconds causes a "Button Stuck" error. With the "Button Stuck" error, the device will automatically exit "Manual" mode and enter "Monitor" mode. The user cannot apply therapy while the device is in Monitor mode. (Z-1683-2010)
Cardiac Science	***Powerheart*** Automated External Defibrillator	II	The K302 relay switch may experience early failure. If K302 contacts are open at the time of rescue, there is a possible delay in therapy or failure to deliver therapy. (Z-1810-2010)
Cardiac Science	Treadmill	II	Treadmills may not have received adequate electrical-safety testing prior to being shipped from the factory. (Z-1757-2010)
Cardiac Science	***Powerheart***, ***Responder***, ***CardioVive*** and ***CardioLife*** Automated External Defibrillators	I	Potential for devices to not deliver therapy. (Z-0765/0778-2010)
Cardima	Surgical Ablation Probe Electrosurgical Cutting and Coagulation Device	II	The sterile pouch in which the product is packaged may be compromised, which could result in patient infection. (Z-2580/2581-2010)
CareFusion	***NicoletOne*** vEEG System	II	CareFusion is voluntarily implementing a field correction to delete certain ***NicoletOne*** software protocols, which users may interpret incorrectly when conducting patient evaluations. (Z-1256-2010)
CareFusion	***Alaris*** PC Unit	I	Under certain wireless network conditions, a communication error can occur, which freezes the PC unit screen, resulting in a delay of therapy. (Z-0006-2011)

Manufacturer	Product	Class	Reason
CareFusion	***EnVe*** Ventilator	II	Ventilator does not fully meet applicable standards for immunity to electromagnetic interference when tested in the laboratory environment. (Z-0857-2010)
CareFusion	***Alaris*** PC Unit	II	PC unit, when used with pump or syringe modules, may, under certain conditions, display an incorrect total dose when programmed to deliver a bolus dose. (Z-0492-2011)
Carwild	Various Surgical Patties	II	Surgical pattie X-ray stripe may become detached. (Z-0093/0095-2011)
Cenorin	Various High Level Disinfection Systems	II	The water-level sensor switch is sensitive to externally induced vibration noise and it produces a false signal that the water level in the tank is full while it is only 75% full. It could present a health risk of biological hazard because the medical devices are not being adequately cleaned or pasteurized with enough water. (Z-0036/0039-2011)
Centurion Medical Products	***Preemie*** Packs; Full-Term Meconium Packs	I	Pediatric tracheal tubes used in the kits were manufactured with an internal diameter smaller than indicated in the label, which could result in an inability to remove secretions and cause partial or complete obstruction of the airway. (Z-0105/0106-2010)
Centurion Medical Products	Basic Core Pack	II	The firm is conducting a sub recall of kits containing ConMed ***Goldline*** rocker switch pencils. The pencils' activation switch may remain in the "on" position after the switch has been depressed with excessive force, thereby continuously activating the pencil. (Z-1595-2010)
Centurion Medical Products	Dialysis On/Off Kit; C.A.P.D. Tubing Exchange Tray; Dialysis Tray	II	The micropore tape is under recall due to the tape not performing and needles becoming loose and dislodged. (Z-1936/1938-2010)
Cepheid	***Xpert*** Blood Culture Test	I	The firm is receiving reports of inaccurate results, which may result in delay of care for seriously ill patients. (Z-1898-2010)
Churchill Medical Systems	Bag Access Device with ***Smartsite*** Needleless Injection Site	II	Bond between the spike and needle may leak, break or detach, resulting in leakage or spillage of chemotherapeutic agents. (Z-1639-2010)
Churchill Medical Systems	***Vycon Nutrisafe 2*** Syringes	III	Feeding syringes were mislabeled. (Z-1203/1204-2010)
Cincinnati Sub-Zero Products	***FilteredFlo*** Cardiac Blanket; ***Temp-Pad*** Cold Therapy Pad	II	Sterilizer equipment was creating incomplete seals in the packaging materials. When the seal is compromised, the sterility of the product inside the package cannot be assured. (Z-0781/0782-2010)
Circaid Medical Products	***Juxta-Lite*** Compression Wraps	II	Some systems have built-in pressure-system lines with the incorrect amount of spacing. (Z-1684/1702-2010)
Civco Medical Instruments	***Surgi-Tip*** Transducer Cover	II	Polyethylene material did not have proper treatment applied during manufacturing. Untreated polyethylene material does not maintain a secure seal with the adhesive tape used to secure the tip to the cover. (Z-2242-2010)
Computerized Medical Systems	***Elekta XiO*** Radiation Treatment Planning System	II	Under certain circumstances, the device will over-estimate the dose in the region where the backup jaw is inside the MLC opening. (Z-1655-2010)
ConMed	Various ***Goldline*** Hand Controls; ***ClearVac Goldline*** Rocker Switches	II	Electrosurgical pencil may remain activated or self-activate after power switch is released. (Z-1562/1573-2010)
ConMed	Arthroscopy Tubing Set	II	Product may have a breach in the seal that could potentially compromise the sterility of the contents. (Z-2192-2010)

Manufacturer	Product	Class	Reason
Continental Medical Labs	Xenon Diagnostic Circuit Kits	II	A component of the kit is being recalled because the filters may have a leak at the seam where the two halves of the filter are bonded together. (Z-1754-2010)
Cook	***Ciaglia Blue Rhino G2*** Advanced Percutaneous Tracheostomy Introducer Sets and Trays	I	Set and/or tray products include a tracheotomy tube component that has been associated with cuff leakage. (Z-2076/2092-2010)
Cook	Ten- and Six-Shooter ***Saeed*** Multi-Band Ligators	II	A section of the ligator barrel may separate from the barrel's friction fit adapter that attaches to the patent end of the endoscope. This could result in a section of the ligator barrel detaching inside the patient's gastrointestinal tract. (Z-0091/0092-2011)
Cook	Novy Cornual Cannulation Set with Clear Tip	II	The distal tip may separate from the catheter while the catheter is in the patient. (Z-1137/1138-2010)
Cordis	***Avanti+*** Introducer	II	A visual irregularity was detected in packing trays. (Z-1421-2010)
Cybernet Systems	***MedStar*** Telemedicine System	II	A software problem renders the devices incapable of capturing lung function, oxygen saturation and pulse data collected from multiple tests in accordance with the instructions for use. (Z-0852/0855-2010)
Cyberonics	VNS Therapy Demipulse Generator	II	Battery-life projection is inaccurate. (Z-1591-2010)
Datex-Ohmeda	***Aisys*** and ***Avance*** Anesthesia Systems	I	The control board wiring harness may have a defect, which can cause the machine to unexpectedly shut down, terminating ventilation, anesthetic delivery and potentially patient monitoring. (Z-1526/1527-2010)
Datex-Ohmeda	***Aisys*** Anesthesia System	II	Users may inadvertently leave a test plug in the inspiratory flow sensor after completing a "Low P Leak Check" on the "Switched Common Gas Outlet" configuration of ***Avance***, ***Amingo*** and ***Aisys*** anesthesia machines that may impact patient safety. (Z-0008/0010-2011)
Davol	Bard ***Ventrio*** Small Oval Hernia Patch	II	Patch is mislabeled. (Z-1536-2010)
Defibtech	***Lifeline*** and ***ReviveR*** AED Semiautomatic External Defibrillators	I	When used with an affected battery pack, the AED may falsely detect an error condition, cancel the charge and not provide therapy. (Z-1781/1782-2010)
Defibtech	DDC-6-AA Data Card	II	Data cards may include an incorrect format, which may cause the AED to not function correctly. (Z-0077-2011)
Dental EZ	***Titan 3*** 5K Low-Speed Motor	III	The housing of the 5K motor is labeled as a 20K motor. (Z-2354-2010)
DePuy	ASR Acetabular Implants	II	New data regarding the ASR platform suggests a higher-than-expected revision rate for the ASR XL ***Monoblock*** Metal-on-Metal (MoM) System linked to usage of Monoblock MoM cups with corresponding head sizes below 50 mm in diameter. (Z-2031/2059-2010)
DePuy	***Summit*** Broach Handle	II	Handles are experiencing early failure due to a weakened handle locking mechanism. (Z-0013-2011)
DiaDexus	PLAC Test Reagent Kit	II	Some samples may return with falsely elevated results, potentially as a result of an interfering substance. (Z-1748/1753-2010)
DiaDexus	PLAC Test ELISA Kit	II	The kit failed stability prior to expiration, affecting samples with results less than 500 ng/ml. (Z-0429-2011)
Diagnostic System Laboratories	IGFBP-3 Immunoradiometric Assay (IRMA) Kit	II	IGFBP-3 levels may not be in agreement with simultaneously measured levels of IGF-1. (Z-2607-2010)

Manufacturer	Product	Class	Reason
DiaSorin	***GammaCoat*** Plasma Renin Activity 125 I RIA Kit	II	The kit control provided with the ***GammaCoat*** kit was labeled with the incorrect range. (Z-1914-2010)
Draeger	***Oxylog 3000***	II	Patients received insufficient ventilation. The instructions are inadequate relating to dead-space volume. (Z-0018-2011)
Draeger	***Infinity Delta*** and ***Gamma*** Patient Monitors	II	Monitor keys may become inoperative or activate spontaneously. This may cause a membrane switch-panel malfunction, which could result in the monitor discharging a patient automatically. (Z-2283/2284-2010)
Draeger	***Delta*** Monitors	II	Monitor is rebooting/resetting. (Z-0582-2010)
Draeger	Steris ***Harmony*** Surgical Light	II	A welded seam at the joint of the spring-loaded arm of the surgical light broke as a result of a crack that slowly developed over time. (Z-0414-2010)
Dreamcon	***Fancy i Color*** Cosmetic Lens	II	The lenses are not approved by FDA. (Z-1756-2010)
Dynamic Imaging	***Centricity*** Software	II	Use of built-in reconstruction functions may result in incorrect anatomic orientation markers. (Z-1394/1395-2010)
EBI	***Array*** and ***Polaris*** Spinal System Medium Cross Connector	II	One of the two connector ends of the medium cross connector may not be fully secured to the rod after tightening. This may not be readily apparent to the operating surgeon, resulting in inadequate torsional stability. (Z-0131-2011)
Edwards Life-Sciences	***Fogaty*** Occlusion Catheter	II	The two parts of the tubular package became loose under the shrink wrap that holds the DFU on the packaging tube. (Z-0002-2010)
Edwards Life-Sciences	MHANM8 Pressure Slave Cable	II	Cable wired incorrectly. (Z-0160-2011)
Edwards Life-Sciences	Protection Cannulae Monitoring and Infusion Set	II	Set connectors may break during manipulation. (Z-0542/0543-2011)
Egon Faulhaber Pinzetten	***Rees*** Insulated Forceps	II	The forceps insulation may have cracks or breaks in the insulation that may cause burns to patients when used. (Z-2392-2010)
Electri-Cord Manufacturing	AC Power Cords	II	Power cords may crack and fail inside the plug. There is a potential for fire hazard. (Z-0662/0667-2010.
Elekta	***Leksell GammaPlan*** (LGP)	II	The precision of the calculation used to create the fused study in LGP 8.0 is too low and should not be used until the system is upgraded to LGP 8.2. (Z-1604-2010)
Elekta	***Leksell*** Gamma Knife Perfexion	II	Need to modify the closing speed of the shielding doors in the event of an emergency exit. (Z-1158-2010)
Elekta	***Leksell*** Gamma Knife Perfexion with ***Extend*** Frame System	II	The anterior fixation bar of the ***Extend*** mouthpiece frontpiece may separate from the dental impression tray. This may result in reduced treatment accuracy. (Z-0163-2011)
Elekta	***Leksell*** Gamma Knife C	II	Knife improperly adjusted trolley for 4 mm helmet, which caused jamming when helmet-changer attempted to lock helmet. Lock did not fully engage and could still be raised. When the lock does not engage, and when the helmet changer rises, the helmet could disengage from the helmet changer and fall back onto the helmet trolley. (Z-1533-2010)
Elekta	***Leksell*** Gamma Knife	II	The old sleigh became obsolete due to insufficient locking of the helmet in combination with the new actuator. (Z-1236-2010)

Manufacturer	Product	Class	Reason
Elekta	***Leksell*** Gamma Knife ***Perfexion***	II	The frame adapter might lock the stereotactic frame in the wrong position. (Z-1232-2010)
Elekta	***Leksell GammaPlan***	II	Although the co-registration looks good during the verification step in the co-registration dialog, the obtain transformation may include an error that depends on the voxel sizes and acquisition parameters of the co-registered image studies. (Z-1134-2010)
Elekta	***PrecisePlan*** Treatment Planning System	II	The new "DICOM CT with Body Outline" method to create a patient case in ***PrecisePlan*** may produce incorrect results for some customers. (Z-1109-2010)
Elekta	***iView GT*** Electronic Portal Imaging Device	II	Image problems that have an effect on patient position corrections and on the accuracy of the radiation treatment. (Z-1436-2010)
Elekta	***Synergy***	II	Installation of a touchguard to prevent injury to patients or staff by stopping machine movements in the case of accidental collision. (Z-1441-2010)
Elekta	***Precise*** Treatment Table	II	Bolts supplied with the table sheared off, resulting in the inability to operate the powered table. (Z-1432-2010)
Elekta	***Synergy XVI***	II	A failure in the position detection system could result in incorrect positioning of the detector in the longitudinal or lateral direction. (Z-1411-2010)
Elekta	***Synergy XVI***	II	It is possible to do couch corrections twice. (Z-0350-2011)
Elekta	***Precise*** Digital Accelerator	II	Larger-than-expected variations in wedge factory with gantry rotation. (Z-1159-2010)
Elekta	***Synergy XVI*** Medical Linear Accelerator	II	Two or more CT reference data sets may be necessary for one patient. (Z-1405-2010)
Ellex Medical	Motorized Safety Filter	II	Potential for two screws – important in the design of the safety filter – to come loose. (Z-0577/0578-2010)
Encision	AEM Disposable Electrode	II	Electrosurgical electrode tip insulation may crack and break off during use. (Z-1539/1546-2010)
Encompass	***Thermoflect***	II	The products are not compatible for use in the magnetic resonance imaging (MRI) environment. (Z-1175-2010)
Encore Medical	***Foundation*** Knee Revision Baseplate	II	Central-locking screw was missing threads. There is a potential for dissociation because the screw is not able to be used as a secondary fixation method. (Z-0826-2010)
Encore Medical	***Foundation*** Knee System	II	Pegs are larger-than-specification. (Z-1255-2010)
Encore Medical	***3DKnee*** System	II	Incorrect color label, which is a secondary visual indicator for sizing. (Z-1433-2010)
Encore Medical	***Mika Speedblock***	II	A crack or complete fracture in the anterior chamfer cut slot may occur. (Z-2164-2010)
Encore Medical	***3DKnee*** Baseplates	II	Incorrect color label, which is a secondary visual indicator for sizing. (Z-2244-2010)

Manufacturer	Product	Class	Reason
Encore Medical	Glenoid Head Inserter	II	Product's distal threaded tip may fracture under certain circumstances. (Z-2636-2010)
Endologix	***Powerlink*** System with ***IntuiTrak*** Delivery System	II	The product has the potential for the polyimide tubing to detach from the inner core due to the bond failure. If this occurs, it is likely that treatment will be interrupted. (Z-0593/0594-2010)
Endotec	Knee, Shoulder, Hip and Ankle Prosthesis; TMJ Components	II	Sterility issues involving validation, process variations and test results. (Z-1621/1627-2010)
Escalon Medical	PD Access Vascular Access Devices	II	The packaging may potentially become damaged, compromising the sterility of the product. (Z-0132-2011)
Ethicon	***Vicryl Rapide*** Braided Coated Synthetic Absorbable Suture	II	Channels in the packaging seal can lead to suture degradation and loss of package integrity. (Z-1608-2010)
Ethicon	***Enseal Trio***	II	The weld that connects the electrode to the active rod was separated. This connection is critical to the proper function of these devices. If the weld is separated, the product will not deliver energy to the jaws, resulting in the potential for a cut/transection without a seal. (Z-2635-2010)
Ev3	***SilverHawk*** Peripheral Cutter Driver Plaque Excision System	II	Damage to packaging. (Z-1162-2010)
Ev3	***Protege EverFlex*** Self-Expanding Biliary Stent System	II	Wrong stent size. (Z-1598-2010)
Ev3	***TrailBlazer*** Support Catheter	I	Catheter may crack near the radiopaque marker band at the distal end of the device during use. Cracking of the catheter shaft in this location can result in material separation and potential embolization. (Z-0497-2010)
Excelsior Medical	Disposable Syringe with Normal Saline	I	There is the potential for a dimensional issue, causing leakage and/or loss of sterility. (Z-0035-2011)
Exelint International	Pump-Fill Kit	I	Huber needles included in the pump-fill kits are labeled as non-coring, but they could core 60% to 72% of the time. (Z-1140-2010)
Ferndale Laboratories	***Detachol*** Adhesive Remover	II	There is a defect on the neck surface of the bottles, causing them to leak. Bottle defect may potentially cause contamination of solvent stored in bottles. (Z-0142-2011)
FHC	***microTargeting*** Drive System with Mounted Accessories; ***STar*** Drive System; microTargeting Drive DBS Lead Holder; Depth Stop Adapter	II	Fixation thumbscrew on the DBS depth-stop adapter may be overtightened and damage the implantable lead. (Z-0311/0314-2011)
FHC	***microTargeting*** Guideline Software	II	The raster tab for the software may assign incorrect depths for waveform recordings. If used to identify the implantation target for the DBS lead, the implant may be placed in the wrong location. (Z-1143-2010)
First Quality Hygienic	***Life*** Brand Plastic Applicator Tampons	II	Product package contained incorrect tampons. (Z-2466-2010)
Fresenius	***Liberty*** Automated Peritoneal Dialysis Systems	II	Cycle set cassettes may leak due to holes/scratches in the film, contaminating dialysate and potentially resulting in peritonitis. (Z-0103/0105-2011)

Manufacturer	Product	Class	Reason
Fresenius	Various ***Fresenius*** Devices; Main Power Supply Assembly and AC Power Cord Assembly for Hemodialysis Machines and ***Granuflo 1*** Mixers	II	Power cords may fail if the prongs crack or fail at the plug, and may become a fire/burn/shock hazard or delay/interrupt therapy. (Z-2224/2227-2010)
Fresenius	***Optiflux*** Dialyzer	II	Hemodialyzer may leak at the header/end cap. (Z-1951-2010)
Fujirebio Diagnostics	***Architect*** Tacrolimus Reagent Kit	II	There are reagent barcode-read errors when using reagent due to the print quality of the barcode. (Z-0068-2011)
Fujirebio Diagnostics	***Architect*** Sirolimus Reagent Pack	II	The assay is exhibiting higher-than-normal reports of barcode-read errors. (Z-2172-2010)
G3 Medical	***V. Mueller*** Peanut Sponges	II	Sterile product packaging contains weak seals, which may result in compromised product sterility. (Z-2296-2010)
Galt Medical	Micro Introducer Kit	II	Potential problem with pouch seal, thus affecting sterile product. (Z-1592-2010)
Gauthier Biomedical	Quick Connect Adapter	II	Adapters are able to come apart when a retaining ring in the proximal end of the adapter can dislodge from the retaining ring groove, and the two ends of the adapter fall apart and are unable to be reassembled without special tools and knowledge of the instrument. Also, the adapters have a wobble between the two ends. This is caused when the distal and proximal ends of the adapter assembly were welded non-concentric to one another. (Z-1399-2010)
Gauthier Biomedical	Spinal Implants; ***Pillar SA Peek*** Spacer System Instrument Case	II	***Pillar SA*** implant insertion instrument may experience resistance in turning the activation knob while releasing an implant after intra-operative positioning. (Z-0641-2010)
General Electric	Various ***Innova*** Systems	II	When using the "Worklist" function to import patient data to ***Innova***, there are two scenarios that will cause the next exam to fail and the inability to recall acquired sequences. (Z-1659/1661-2010)
General Electric	Seno ***Advantage*** Workstations	II	When using the "Print Image" or "Print Screen" feature, the "Scale Factor" annotation printed on hardcopy images is inaccurate. Secondary-capture images displayed on the screen and secondary-capture hardcopy images may also contain inaccurate scale-factor annotation. This issue may result in a potential miscalculation of size. (Z-1747-2010)
General Electric	Datex-Ohmeda ***TruSat*** Pulse Oximeter and Accessories	II	It is possible that the external power supply could leak electrical current. This current could cause third-degree burns or an abnormal heart rhythm that, if untreated, could lead to death. (Z-1814-2010)
General Electric	Various ***Innova*** Systems	II	A potential loss of gantry and table motions that may impact patient safety. (Z-1921/1923-2010)
General Electric	Various ***Innova*** Systems	II	Fluoro battery degradation could occur due to long storage conditions impacting the life expectancy of sealed cell batteries. (Z-0407/0410-2011)
General Electric	Various ***Innova*** Systems	II	A potential video-splitter failure could occur with no advance warning, preventing X-ray image display. (Z-0392/0393-2011)

Manufacturer	Product	Class	Reason
General Electric	Various Seno ***Advantage*** Mammo Workstations	II	The measurement values provided by the workstation may be incorrect when applied to magnification images acquired on non-GE digital mammography systems. If not noticed by the caregiver, this could lead to an overestimate of the size of the breast lesion that may impact patient treatment and safety. (Z-0476/0477-2011)
General Electric	***Signa Excite*** Magnetic Resonance Systems	II	System may experience an image flip along the phase encode direction and incorrect annotation, which may result in incorrect localization of anatomy in oblique axial images with the pulse sequences. (Z-0462-2011)
General Electric	Various ***Centricity*** Software	II	Dragging and dropping images may cause flipping of images, which may impact patient safety. (Z-1402/1403-2010)
General Electric	***MAC 800*** Resting ECG Analysis System	II	When more than one ECG report in the file manager is batch-printed in laser print, the potential exists for an incorrect patient identification or name to be displayed on the printout. Misidentification of patient data potentially contributing to delayed or incorrect treatment is then possible. (Z-0645-2010.)
General Electric	***Innova*** Biplane Cardiovascular Imaging Systems	II	A potential limit-switch failure could occur due to collision between the lateral plane of the ***Innova*** Positioner and other equipment in the room. This collision may break the X-ray and positioning switches, and may not allow exam completion. (Z-0540-2010)
General Electric	Various ***Voluson*** Diagnostic Ultrasound Systems	II	When using the combination of 2D-CRI and PW with a steered Doppler angle, the displayed velocity scale is incorrect. The consequence can be an underestimation of flow velocities in the range of 30% to 60%. This operating procedure is typically used for quantification of carotid stenosis. The degree of the stenosis may be inaccurately quantified, which may result in a delay in treatment. (Z-0541-2010)
General Electric	***Omega*** Tables	II	Due to the potential weakness of some table rotational brakes, an unintended table rotation may occur while the table is locked. This issue could lead to a patient fall if the unintended motion occurs during patient transfer. (Z-0616/0621-2010)
General Electric	***OEC 9900 Elite*** ESP and GSP Fluoroscopes	II	A software defect may result in a false indication and warning on the ***OEC 9900*** workstation and C-arm display that the X-ray tube anode is overheated. This will cause the displayed air-kerma rate and cumulative air kerma to be inaccurate. (Z-0004/0005-2010)
General Electric	Various ***Infinia*** Devices	II	Failure to provide the complete user manual information. (Z-0494/0496-2010)
General Electric	***iDXA***; ***Prodigy*** 1-8 Series; ***DPX-NT*** Series; ***DPX-MD*** Series; ***DPX-Bravo/Duo***	II	Failure to properly pre-indicate the technique factors to be used during a patient scan. (Z-0600/0604-2010)
General Electric	***Discovery CT 750*** HD; ***LightSpeed VCT*** 7.2 Vision	II	Failure to properly document the CTDI in the technical reference or user manual. (Z-0668/0669-2010)
General Electric	***ApexPro*** Oximeter Systems	II	Potential misuse of the ***ApexPro*** and incorrect message and alarm information in the operator's manual may impact patient safety. (Z-0631-2010)

Manufacturer	Product	Class	Reason
General Electric	***Carescape*** Monitor	II	Four potential safety issues: Loss of user input when using certain displays or the USB remote control; potential for a delay in treatment or missed alarm when the alarm light is used as a primary alarm source and audible alarms are turned down or off; monitor will not use user-entered hemoglobin values when calculating Sv02 values, which could result in incorrect treatment of a patient; and when used in conjunction with Tram, the HR alarm limits may revert back to default settings, which could result in a missed alarm. (Z-2275-2010)
General Electric	***Carescape*** Monitor Software	II	There is a safety issue associated with the monitor when monitoring ECG. The safety issue includes the potential for a delay in treatment. (Z-1801-2010)
Genzyme	***Biosurgery*** Essentials Kit	II	Revised labeling of kit clarifies the non-sterile packaging of the outer clear plastic tray, which should not be opened in the sterile field. (Z-2310-2010)
Gesellschaft Fur Medizinische	***Licox*** Brain PMO Probe Kit	II	The outer boxes of the kit are labeled with an incorrect shelf-life date. (Z-0161-2011)
Gesellschaft Fur Medizinische	***Integra***	II	One probe that failed a product release test was inadvertently packaged and released into inventory in Integra's distribution center. (Z-1422-2010)
Gibson Laboratories	***RambaChrom*** Devices	II	Discrepancies between the product package label and technical insert are conflicting and may be misleading to user. The product insert should have indicated for "Research Use Only" instead of for "In Vitro Diagnostic Use." (Z-0827/0828-2010.)
Greatbatch Medical	***Enpath*** Leads	II	The silicone tubing was processed outside of validated parameters. Although the material remains biocompatible, test data regarding the performance characteristics are not available. (Z-0581/0581-2010)
Greatbatch Medical	***Enpath*** Leads	II	Packaging is labeled as "unipolar leads," but the lead body itself is correctly labeled as "bipolar." This could result in a bipolar lead being implanted with a pulse generator operating in unipolar mode. (Z-0287-2011)
Greatbatch Medical	***OptiSeal*** Valved PTFE Peelable Introducer	II	The outer sterile barrier packaging is not intact. (Z-2294-2010)
Guidant	***Teligen***, ***Cognis***, ***Confient***, ***Livian***, ***Vitality***, ***Contak Renewal*** and ***Ventak Prizm*** Defibrillators	II	Boston Scientific has stopped shipment and is retrieving un-implanted devices from U.S. hospitals of all implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) after determining that some manufacturing process changes were not submitted for approval to FDA. (Z-1553/1559-2010)
Gyrus Medical	***Micron*** Bobbin Vent Tube	I	Product may have been shipped without being sterilized. (Z-0797-2010)
Gyrus Medical	***ACMI Pleatman*** Sac Tissue Removal System	II	Due to a manufacturing error in the production of the trays, it is possible that a crack could form that would compromise the package integrity, and possibly the sterility of the packaged device. (Z-2436-2010)

Manufacturer	Product	Class	Reason
Gyrus Medical	***ACMI***	II	Lack of sterility assurance due to compromised package seals. (Z-2651-2010)
Gyrus Medical	***VAPR*** Electrodes	II	Product does not meet the packaging specifications for pouch seal integrity, which could lead to a breach in sterility. (Z-2297/2309-2010)
Gyrus Medical	***ACMI PKS*** Seal Open Forceps	II	The metal shim between the jaws may detach during the procedure and fall into the surgical field. The detached shim may be undetected and be left behind in the patient. This could subsequently cause complications. (Z-0632/0637-2010)
Haag Streit	***Lenstar*** Software	II	The ability to perform a manual adjustment of the retinal thickness measurement was not disabled for products targeted for U.S. distribution. The current software allows the user to manually alter the retinal thickness measurement, which could modify the automatic axial eye-length measurement, resulting in the selection of an incorrect intra-ocular lens. (Z-1897-2010)
Hemostatix Medical Technologies	***Hemostatix*** Handle	II	Lack of sterility assurance. (Z-2595/2596-2010)
Hill-Rom	***TotalCare*** Bed	II	The controls on the intermediate rail may fail to function. (Z-1065-2010)
Hill-Rom	ExcelCare Bariatric Beds	II	The siderails could experience false latching, unintentional lowering or become inoperable. (Z-0332/0333-2011)
Hill-Rom	***Affinity Four*** Birthing Bed	II	The brakes may not hold or lock. (Z-0548-2010.)
Hitachi Medical	Various ***Airis*** Scanner Compensation Coils	II	The coil could fall, contacting the patient table and potentially putting a patient at risk. (Z-1616-2010)
Hocoma	***Lokomat*** System	II	Changes to stored sensitivity values may occur and lead to higher limits in the force and trajectory deviation. (Z-0590-2010)
Hologic	***ATEC*** Breast Biopsy and Excision System	II	The product is labeled as ***ATEC*** 0912-12, but it actually contains an ATEC 0912-20. (Z-2285-2010)
Hologic	***ATEC*** Breast Biopsy and Excision System	III	The product is labeled as ***ATEC*** 0909-12, but it actually contains an ATEC 0909-20. (Z-1160-2010)
Hospira	Various Device Products by Hospira	II	A component used in the device may cause sparks/flashes, and poses a fire and shock hazard. (Z-0011/0034-2010)
Hospira	***Symbiq*** One- and Two-Channel Infusers	I	The infusion pump fails to detect air-in-line conditions during operation. (Z-1894/1895-2010)
Hospira	***Symbiq*** One- and Two-Channel Infusers	II	The clamp may not secure to the I.V. pole, and the pump may slip or fall off. The pump may fall on a person or pull the tubing out of the I.V. container. (Z-2390/2391-2010)
Hospira	***Symbiq*** One- and Two-Channel Infusers	I	Motor-encoder failures in the pumping mechanism cause the infuser to cease operation during infusion therapy, resulting in delay or interruption of infusion therapy. (Z-0127/0128-2011)
Hospira	***LifeShield*** Sets	II	There is a potential for fluid to leak from the back-check valve, which could result in inaccurate delivery and occupational exposure. (Z-080/0809-2010)

Manufacturer	Product	Class	Reason
Hospira	***GemStar*** Pump Set	II	Under-delivery of infusion during clinical use at low-rate settings (less than 10 mL/hour). Patient may not receive the intended amount of medication. (Z-2627/2633-2010)
Huangshan City Shexian Comfort Massanage Applia	***ReliaMed*** Deluxe Portable Adjusting Table	II	The vinyl-covered, padded plywood table surface may break near the foot end. (Z-2288-2010)
Hydrofera	Femoral Sponge; Bio-Prep Bone Preparation Kit with Merocel Sponge; Advanced Cement Mixing Bio-Prep Cement Application Kit; ACM with Femoral Brush and Femoral Sponge; ACM Bio-Prep with Merocel	II	There is potential for a breach in sterility specific to the sterile packaged femoral sponge, which may result in a non-sterile product. (Z-1104/1108-2010)
Hypoguard	***DiaScreen***	III	The front and back panel of the bottle carton lists five reagents when it should only list four reagents. The Ketone reagent should not be included on the label. (Z-2634-2010)
I2s Micro Implantable Systems	Inserter Wand Holder	II	Component of cranial array may not allow sufficient tightening to maintain inserter position. (Z-1619-2010)
Imaging Sciences International	***i-Cat Classic*** 3D Dental Imaging System	II	Overhead carriage drops quickly. (Z-0543-2010)
iMed	Various Types of Pain Pump, Single Shot Needle; Tuohy Catheter Kit; Stimulation Catheter Continuous Nerve Block Tray	II	Defects include, but are not limited to: not sterile; not properly labeled; ineffective drugs and swabs; and breakable catheter tips. (Z-2356/2379-2010)
Impac Medical Systems	Sequencer Verify and Record System	II	Software problem results in the overwriting of patient records with information from a different patient. (Z-0076-2011)
Impac Medical Systems	***Elekta Impac*** Software Sequencer Verify and Record System	II	The database conversion utility used during the upgrade errantly changes the start gantry angle to zero. Any affected treatment fields, if not already treated, would start delivering from zero instead of the original prescribed value. (Z-0159-2011)
Independence Technology	***iBOT 4000*** Mobility System Battery Pack	II	A thermal breaker in the battery pack has the potential to open due to overheating and disable one-third of the cells in the affected battery pack. (Z-1775-2010)
INO Therapeutics	***Ikaria Inomax DS*** Drug Delivery System	I	The pressure switch may fail, which may interrupt or delay the administration of Inomax (nitric oxide) for inhalation to patients. (Z-2176-2010)
Insight Instruments	Cornea Coat Syringe; BIOM Pack	II	Product recalled due to a potential weakness of the peel-pouch seals. (Z-2220-2010)
InSound Medical	***Lyric*** In-Canal Hearing Aid	II	Manufacturing error could result in electrolyte leakage from the product's battery. (Z-1681-2010)
Institut Straumann	Impression Set	III	The label has the incorrect description of an RN solid abutment instead of a WN. (Z-2177-2010)
Instrumentation Laboratory	Various ACL TOP Devices	II	New data check, "Multiple Threshold Check," was added to identify and fail abnormal (bimodal) clot curves. (Z-0135/0138-2011)
Integra LifeSciences	***DuraGen XS*** Dural Regeneration Matrix	II	Test results no longer support a three-year shelf life. (Z-0450/0454-2011)

Manufacturer	Product	Class	Reason
Integra LifeSciences	***NXT Ultra*** Surgical Aspirator Systems	II	A ground-fault malfunction at the rectifier retaining screw may cause the aspiration pump to run at maximum speed and continue to run until the entire system is turned off. This may result in excess aspiration that requires medical intervention. (Z-2637/2638-2010)
Integra LifeSciences	Suction Reservoir Kit	II	The sterility of the product may be compromised. (Z-2588-2010)
Integra LifeSciences	***NeuroBalloon*** Catheter	I	Catheters have the potential to improperly inflate or deflate under certain conditions. (Z-2425-2010)
Integrated Biomedical Technology	***OvuChek*** Saliva Ovulation Disposable Test Strips	II	The ovulation test strips were shipped without 510(k) premarket notification clearance from FDA. (Z-0968-2010)
International Technidyne	***directCHECK*** Whole Blood Control	II	The acceptable performance range published in the package insert is incorrect. (Z-1786-2010)
International Technidyne	***GEM*** Check Coag Whole Blood Controls	II	There is an error in the package insert. The incorrect acceptable performance ranges were published. (Z-2107/2108-2010)
International Technidyne	Integrated Data Management System	III	A tabulation error results in incorrect electronic quality control summary reports. (Z-2438-2010)
Interpore Cross International	***Bio-Eye*** Hydroxyapatite Orbital Implant and Conformer	III	The expiration date of the product was omitted from the label. (Z-2292-2010)
Intuitive Surgical	***da Vinci S*** Surgical System	II	Gripper or scissor jaws may close inadvertently and will not open on command, and various other reported modes of failure. Control by surgeon may fail, and this failure may be difficult to detect. (Z-1161-2010)
Invacare	***Storm TDX SR*** Power Wheelchair	II	The stability lock feature may not engage properly or consistently. (Z-0579-2010)
JLT Engineering Products	Universal Flat Panel Yoke	II	Some of the pitch shafts were not properly welded, which results in the monitor not being level. (Z-1605-2010)
Kamiya Biomedical	K-Assay CRP (3) Calibrator E	II	The long-term stability of Level 2 (1.0 mg/dL) may not be within specifications due to a decrease in CRP concentration. (Z-0973-2010)
KAP Medical	***AccuMax Quantum*** Complete	II	Potential out-gassing of the battery and short-term ignition of the gas within the control-unit enclosure. This failure mode includes a risk of fire. (Z-1216-2010)
KC Pharmaceuticals	Various Brands of Sterile Preserved Saline Solution	II	Affected lots were manufactured between two failed media fills; therefore the lots produced cannot be assured of being free of contamination, and may not be sterile. (Z-1222/1227-2010)
Kentucky Packaging Service	***Midas Touch*** Needle Electrode	II	The electrode has a large diameter shaft that transitions to a smaller diameter shaft. The first layer of insulation, which covers the small diameter shaft, overlaps with the second layer of insulation, which covers the larger diameter shaft. On some electrodes it appears that the overlap is too short to cover the transition, which makes this area vulnerable to insulation damage. (Z-0140-2010)
Kmedic	***Orthofix*** Spinal Implants	II	The Hallmark Anterior Cervical Plate Bender may have a nonconformity, causing difficulty accepting 3-4 Level plates, or the inability to accept 3-4 Level plates that are intended to be additionally contoured. (Z-1653-2010)

Manufacturer	Product	Class	Reason
Lab Vision	***NeoMarkers*** Rabbit Monoclonal Anti-Human Cyclin D1 Antibody	II	May be contaminated with Ki-67 antibody, which could cause abnormal staining patterns and produce false-positive results. (Z-2424-2010)
Leica	***Peloris*** Rapid Tissue Processor	II	Confusion during manually changing reagents, general users running unvalidated protocols and wax-valve leakage have contributed to tissue damage during processing, leading to rebiopsies. (Z-1551-2010)
Leica	***Bond*** Ready-To-Use Primary Antibody Thyroid Transcription Factor-1 (SPT24); Lyophilized Mouse Monoclonal Antibody Thyroid Transcription Factor-1; Liquid Mouse Monoclonal Antibody Thyroid Transcription Factor-1	II	In combination with a sensitive polymer detection system, the TTF-1 antibodies may stain additional tumor types other than what is currently indicated on the instructions for use. (Z-2497/2499-2010)
Leica	Shutter HX SP5	II	A manufacturing defect was identified that could potentially result in the laser shutter not closing as intended. (Z-1221-2010)
Leica	Footswitches	II	The pedals of the footswitch stick and the zoom/focus moves to the end position. (Z-1632/1633-2010)
LeMaitre	Vascular ***AnastoClip GC*** Vessel Closure System	III	The contents section listed on the labels of the medium and large sizes incorrectly identified the size of the clip as "XL." (Z-0164/0165-2011)
LeMaitre	***VascuTape*** Radiopaque Tape	III	The box label lot and expiration date information was switched. (Z-0433/0436-2011)
LifeCell	***Strattice*** Reconstructive Tissue Matrix	III	Product was mislabeled. (Z-2623-2010)
LifeScan	***OneTouch Ultra*** Test Strips	II	***OneTouch Ultra*** Test Strip products may contain ***OneTouch Select*** strips. (Z-2639-2010)
Linvatec	***Concept Grafix*** Tendon Stripper	II	There is a possibility that the device may exhibit hydrogen embrittlement in the material and is subject to potential breakage. (Z-2585-2010)
Linvatec	***Gator***	II	Breach in the sterile barrier. (Z-2503-2010)
Linvatec	***Advantage Turbo*** Two-Button Shaver	II	Product may self-activate due to moisture intrusion into the housing body. (Z-2026-2010)
Lockheed Martin	***Perseus*** Pulsed Fiber Laser	II	The device emits potentially hazardous laser radiation. (Z-1170-2010)
Lumen Biomedical	***Xtract*** Aspiration Catheter System	II	Packaging/storage issue results in compromised integrity and potential product failure during use, leading to potential patient injury. (Z-0445-2011)
Luxottica	Polycarbonate Prescription Lenses	II	The lenses made for sunglass frames do not meet the lens thickness specification established by the frame manufacturer. (Z-0542-2010)
Mainline Technology	***Mainline Confirms*** Urine Pregnancy Test	II	Lack of assurance of safety and efficacy; unapproved for marketing in the U.S.; non-compliant with cGMP regulations; and no stability data to support labeled expiration dates. (Z-1018-2010)
Maquet	Various ***Hanaulux*** Cupolas and Spring Arms; ***XTEN*** Cupolas	II	There is a crack on the front joint of the Acrobat arm. (Z-0182/0188-2010)

Manufacturer	Product	Class	Reason
Maquet	HLM Tubing Set with Bioline Coating	II	Tubing packs may contain defective tubing connectors. Leaks at the shank of the connector may result in air aspiration in the venous line. (Z-0011-2011)
Maquet	***Exxcel*** Vascular Grafts	II	Product mislabeled. Bleeding could occur if the wrong product is used. (Z-0866-2010)
Maquet	***Exxcel*** Vascular Grafts	II	This is an expansion of Recall No. Z-0866-2010, adding an additional two lots to the recall of ***Exxcel*** vascular grafts due to a labeling mix-up. (Z-1606/1607-2010)
Maquet	Servo Ventilators	II	Some ventilators should not be used with a system that may generate negative pressure below -100 cm H20 (closed-system suctioning) due to the risk of damaging the ventilator's pressure transducers. (Z-0588/0589-2010)
Maquet	Various Intra-Aortic Balloon Pumps	II	Although the pump may continue to deliver therapy to the patient, display-related issues may cause the user to be unable to view the pump on the information screen. (Z-1811/1813-2010)
MD Scientific	***EndoTool*** Drug Dose Calculator Software	II	Software did not always provide an audible alert when a blood-glucose measurement was due. This could result in a patient not receiving an appropriate dose of insulin. (Z-0126-2011)
MedTec	Various Civco Extensions	II	The extensions can become detached from the main body of the couch. (Z-0394/0396-2011)
Medela	***Symphony*** Breast Pumps	II	The non-sterile devices were erroneously packaged with instructions stating the devices are sterile and do not require cleaning before first use. (Z-1442-2010)
Medela	Single/Double and Double Breast Personal Accessory Convenience Kits	II	The product sterility may be compromised due to possible pinholes in the rigid tray of the package. (Z-2483/2486-2010)
Medica	***EasyRA*** Cuvette Segment 1	II	Chemistry analyzers may report calcium results below the sample's actual concentration. Reported results may be 10% to 15% lower than expected sample results. (Z-0078-2011)
Medical Components	***Dignity*** Low Profile CT Port	II	Product was packaged with the incorrect port and does not match the label. (Z-2235-2010)
Medical Components	***Bioflex Tesio*** Kit with Cutting Trocar	II	Product mislabeled. (Z-0161-2010)
Medical Device Technologies	***Tru-Core II*** Automatic Biopsy Instruments	II	Compromised packaging integrity. (Z-0025-2011)
Medical Flow Systems	***SmartInfuser PainPump***; ***Smart-Block*** Pain Management System	II	Product leaks associated with a new pump reservoir, and incident related to regulator fast-priming feature. (Z-1021/1022-2010)
Medical Product Specialist	Various I.V. Sets with Small and Macro Bores	I	A manufacturing deviation could cause the product to not function properly, possibly resulting in an air embolism. (Z-1076/1080-2010)
Medical Systems	***Fabius*** Anesthesia Machines	II	Potential failures with the AC power cord made by Electri-Cord Manufacturing. (Z-2478/2479-2010)
Medrad	***Avanta*** Fluid Management Injection System	II	The product may be defective, resulting in a reduction of the saline delivery rate and inadequate air purging. (Z-1199-2010)
Medrad	***Stellant CT*** Dual Syringe Kits	II	Kits contain a T-connector that may be susceptible to cracking, breaking or leaking. (Z-1954-2010)

Manufacturer	Product	Class	Reason
Medtrol	***CaviBleach*** Wipes	II	The disinfectant wipes were found out-of-specification for the disinfectant activity prior to the expiration date. (Z-1815-2010)
Medtronic	Orthopedic Dovetail Clamp	II	Clamp may slip if used with a non-indicated system, resulting in the potential display of inaccurate navigation information. (Z-0923-2010)
Medtronic	***U-Clip*** Double Arm Approximation Device	II	The clip's release mechanism becomes separated from the needle assembly. These instances of separation have occurred when pulling the clip through prosthetic material or when grasping and releasing the clip using robotic instrumentation. Separation of the release mechanism during handling or deployment could result in the release of small components into the body. (Z-2030-2010)
Medtronic	***Navigation*** O-Arm Imaging System	II	Breakage of the door cable during opening and closing may occur and cause physical harm or delay of therapy. (Z-0447-2011)
Medtronic	***Sprint Quattro*** Devices	II	Over-retraction of the helix during initial implant or subsequent repositioning may result in the inability to extend the helix. (Z-0474/0475-2011)
Medtronic	***Max Drill*** Guide	II	Drill guide handle may detach unintentionally during use. (Z-0145-2011)
Medtronic	Intrathecal Catheter Spinal Segment Revision Kit	II	Introducer needles in the kits may exceed USP requirements for bacterial endotoxin. (Z-0334/0335-2011)
Medtronic	***Ideal Maxpac*** Total System; ***One Source*** Pack	III	The "Use Before Date" (UBD) on the outer label of the kit/pack does not accurately reflect the UBD of the components within the kit/pack. (Z-0868/0869-2010)
Medtronic	Hospital-Grade Power Cord	II	The power cord's prongs may crack and fail at/or inside the plug. (Z-1939-2010)
Medtronic	***HMS Plus*** Hemostasis Management System	II	The heparin assay controls may run longer than normal and in some cases fail to give an acceptable result. (Z-1537-2010)
Medtronic	***StealthStation*** System	II	Excessive wear at the power cord retractor or incorrect assembly of the power plug may cause sparking, intermittent loss of power or electrical shock. (Z-2029-2010)
Medtronic	***Titan*** Anchor Accessory Kit	II	There is the potential for lead migration as a result of insert separation within the anchor. (Z-500-2010)
Medtronic	Various ***Concerto***, ***Consulta***, ***Maximo***, ***Secura*** and ***Virtuoso*** Devices	II	Software problem. (Z-0110/0118-2011)
Medtronic	Sofamor Danek Extended Length Trocar	II	The trocar may not fully engage with the rod inserter or may prematurely disengage. (Z-0606/0607-2010)
Medtronic	***Midas Rex Legend*** Footed Attachment	II	Component of product attachment may be outside established tolerance with the potential for the footed portion to break during normal use. (Z-0546-2010)
Medtronic	***Repose G2*** Bone Screw System	II	Improper labeling. (Z-0535/0536-2010)
Medventure Technology	***Exodus*** Standard Loop Multipurpose Drainage Catheter with Hydrophilic Coating	II	One box containing five catheters did not complete the sterilization process prior to distribution. (Z-0015-2011)
Merit Medical Systems	University Health System Custom Cardiac Cath Pack	II	A manufacturing defect may prevent adequate sterilization of the entire device. (Z-0744/0748-2010)

Manufacturer	Product	Class	Reason
Merit Medical Systems	Endotek ***Alimaxx-B*** Uncovered Biliary Stent	II	Degradation of the outer portion of the delivery catheter may prevent proper deployment of the biliary stent. (Z-0801/0806-2010)
Merit Medical Systems	Control Syringe	II	Small holes in the packaging may render the product non-sterile. (Z-0061/0066-2011)
Merit Medical Systems	Custom Kit	II	Defective custom kits may draw in air during use, which may compromise patient safety and affect treatment. The valve's fixed luer may be over- or under-tightened, causing leaking at the bond joint. (Z-0552/0559-2011)
Merit Medical Systems	***VacLok*** and ***Merit Medallion*** Syringes	II	Packaging for syringes may have holes that would compromise the sterility of the package contents. (Z-0503/0506-2011)
Merit Medical Systems	Vessel Sizing Angiographic Catheter	II	Marker bands on angiographic catheters may not be properly attached, allowing movement of the bands. (Z-1731-2010)
Merivaara	***Vertier*** Surgical Table	II	In certain positions, product is susceptible to fluid intrusions, which could possibly result in a short-circuit or unsolicited movement. (Z-1238-2010)
Metrix	***Bigger Better Bladder***	II	The device collapsed during a procedure, thereby obstructing flow. (Z-1323-2010)
Microtek Medical	***Stackhouse*** Laser Resistant Suction Probe	II	Product labeled as sterile was distributed without sterilization. (Z-2109-2010)
Mindray	***Datascope AS3000*** Anesthesia System	II	The caster mount may break, causing the wheel to fall off and the unit to tip. (Z-1313-2010)
Mindray	***Passport V*** Monitor	II	The arrhythmia analysis, ST analysis and invasive blood pressure functions are not operational. (Z-1785-2010)
Minntech	DSD Application Guide	II	The DSD hookup application guide incorrectly recommends use of the ***Medivators*** DSD-110-HU0109 endoscope hookup to connect the ***Pentax*** EG-3630U ultrasound endoscope to a Medivators DSD endoscope reprocessor or Medivators Scope Buddy endoscope flushing aid. This may result in inadequate disinfection during reprocessing, and subsequent infection risk to the patient. (Z-2213-2010)
Mira	Finger Probes	II	Devices distributed without an approved 510(k). (Z-1918/1920-2010)
MMJ	Various ***Shiley*** Tracheostomy Tubes	I	Inflatable cuff tracheostomy tubes may leak air, resulting in inadequate ventilation. (Z-1462/1523-2010)
Monarch Labs	Medical Maggots with Accessory ***LeFlap*** Dressing (previously known as ***Creature Comforts II***)	II	A patient developed cellulitis after using maggots from an affected batch. (Z-2207-2010)
Multi-Med	Winged Administration Set; Huber Needles	I	Huber needles may core and result in port leakage or emboli being flushed out of the port. (Z-2506/2578-2010)
Multi-Med	Huber Needles	I	An FDA sample determined that the needles were coring. (Z-1888/1889-2010)
Navilyst Medical	Various ***Vaxcel*** Ports	II	FDA testing determined that non-coring needles included in the ports may result in coring, resulting in septum damage. (Z-1874/1887-2010)
NERL Diagnostics	UCG-Slide Test; UCG-Beta Slide Monoclonal II	III	Specific lots no longer meet their stated limit of detection claims of 2000 mIU/mL for the UCG-Slide Test and 500 mIU/mL for the UCG-Beta Slide Monoclonal II test. (Z-2500/2501-2010)

Manufacturer	Product	Class	Reason
NERL Diagnostics	***Lifesign*** *Staph* Latex Kits; ***Wampole*** *Staph* Latex Test	II	Unreactive *Staph* latex reagent. (Z-1110/1111-2010)
NewDeal	***Panta*** Support Device and Arthrodesis Nail Instrumentation Tray	II	Inability to properly align the calcaneal screw placement on a consistent basis due to a manufacturing defect of the targeting frame. (Z-0308-2011)
NewDeal	***Qwix*** Stabilization Screws	II	The screws were etched incorrectly as "32 mm" instead of "34 mm" length. (Z-1253/1254-2010)
Newport Medical Instruments	***e360*** Ventilator	II	The failure of the pressure transducer results in pressure or volume alarms where P1 cannot be calibrated correctly, or in a device alert alarm associated with a P1 failure. In most cases, the failure is detected at "power on," but failures can occur during ventilation. (Z-1617-2010)
Nexcore Technology	***Enfant*** Pediatric VEP Vision Testing System	III	The computer-based system may lose test counts when the time in the device is changed during a changeover from standard time to daylight savings time. (Z-1437-2010)
NG Instruments	***Mini Max*** Torque Drill Bit	II	The epoxy is flaking off of the drill bits and countersinks. (Z-1430-2010)
Nikkiso Medical Systems	***Aquarius*** System	I	When a certain level of fluid imbalance is detected, the ***Aquarius*** will trigger an alarm. However, users are able to override this alarm and continue therapy. By repeatedly overriding the balance alarm without solving the issue (closed clamp, kinked line, etc.), it is possible to remove too much fluid from, or replace too much fluid to, the patient. (Z-0653-2010)
Ningbo Advan Electrical Co.	Disposable Skin Stapler	II	The sterility of the staplers is questionable. (Z-1610-2010)
Nissho Insurance Services	Huber Needles and Infusion Sets	I	Non-coring needles, when inserted into an implanted port, were shown to core the silicone ports septum. (Z-0638/0640-2010.)
Nova Biomedical	***StatStrip*** Glucose Test Strips	II	Glucose strips report low glucose results. (Z-1783-2010)
Novasys Medical	***Renessa RF*** System	II	The instructions for use were revised to emphasize potential side effects. (Z-1404-2010)
NuMED	***Impact*** Catheters	II	The packaging of the catheter was cracked and deteriorating. (Z-0509-2010)
Ohio Medical	***MobiVac*** Portable Wound Care Pump; NPWT Small Mobile Bag	II	Parts were separated while in an enclosed nylon transport bag during use. (Z-1777/1778-2010)
Olympus Winter & IBE	Trocar Spikes	II	Weak weld seams. (Z-1163-2010)
Optima Healthcare	Hill-Rom Beds	II	The flexing of the junction of the sleep deck's head and midsections can create excess pressure on the pivot pin E-ring, which could cause the E-ring to come off. (Z-2167/2170-2010)
Optovue	***RTVue*** Optical Coherence Tomography	II	Product marketed without a 510(k). (Z-1131-2010)
Organogenesis	Apligraf	II	Product is contaminated with yeast identified as *Pseudozyma Antarctica*. (Z-2589-2010)
Oridion Medical	Various ***Microstream Filterline*** and ***Capnoline*** Products	II	The filterline may not be recognized by the monitor when connected. No CO2 readings will be displayed and no alarms may sound for unmonitored patients. Replacing the filterline may delay treatment. (Z-1999/2014-2010)

Manufacturer	Product	Class	Reason
Ortho Development	Distal Centralizer	II	The hip stem did not fit the distal centralizer because the hole was not drilled with the appropriate taper. (Z-0315-2011)
Orthofix	***XCaliber*** Meta-Diaphyseal and Ankle Complete Kits	II	There is a potential for breakage of the clamp when locking the cam. (Z-1434/1435-2010)
Orthofix	Bone Taps	II	Non-cannulated modular bone taps used with the ***Firebird*** Spinal Fixation System may contain a manufacturing nonconformance, resulting in the taps creating a single-lead-screw thread rather than the required dual-lead-screw thread. (Z-1611/1615-2010)
Orthopediatrics	IM Femoral Nails	III	The potential exists for the nails to fracture during insertion of the nail. (Z-0339/0364-2010)
Osypka Medical	***Oscor PACE***	II	Failure to watch for, and appropriately respond to, error messages provided by the pacemaker may terminate stimulation and possibly cause a life-threatening situation for a pacemaker-dependent patient. (Z-2443/2444-2010)
Oxoid	CM0225 Brain Heart Infusion I.V.D	II	Failure to grow quality control strains of *Streptococcus pneumoniae*. (Z-0979-2010)
Oxoid	AdvanDx *E. coli/P. aeruginosa* PNA FISH Culture Identification Kit	II	Strains of *Acinetobacter radioresistens* cross-react with both *E. coli/P. aeruginosa* PNA FISH and EK/*P. aeruginosa* PNA FISH to produce a false-positive red signal. (Z-0490-2011)
Pelton & Crane	***Chairman*** and ***Spirit*** Dental Chairs with Magnetic Headrests	II	Magnetic headrests may affect patients with implantable pacemakers and defibrillators. (Z-1179/1180 & 1327/1326-2010)
Pelton & Crane	***Spirit 3000*** Dental Chair	III	The dental chair lacks a valid device history record. (Z-1311-2010)
Pentron Clinical Technologies	***Bond-1*** Primer/Adhesive	II	Some of the material has been found to be gelled, and therefore becomes unusable. (Z-1150-2010)
Peregrine Surgical	Endo Ocular Directional Laser Probe	II	Product did not have 510(K) clearance. (Z-2652-2010)
Peregrine Surgical	Endo Ocular Adjustable Laser Probe	II	Product did not have 510(k) clearance. (Z-2399-2010)
PerMedics	***Odyssey***	II	Anomaly No. 1 – invalid characters in patient ID error: Currently, ***Odyssey*** considers a valid ID to be comprised of numbers and/or letters. If a patient ID in a study contains a character other than a letter or number (including spaces), Odyssey removes the invalid character when moving it to a patient folder. Due to this, it is possible that two different patient studies could be listed within Odyssey for one patient. Anomaly No. 2 – Odyssey machine library error: The Odyssey machine library contains configuration in formation for each treatment machine, mode, etc. Currently, if the 44 machine library contains treatment modes with two different collimator types (for example, jaws and cones), then it is possible for the software to use the incorrect collimator type when calculating dose. Anomaly No. 3 – Odyssey MLC block error: Odyssey allows the user to add an Odyssey MLC block (a virtual block) to move the MLC leaves automatically to cover a selected tissue region. When a virtual block is used, a block tray would not be expected in setup; however, Odyssey currently considers a block tray transmission factor when calculating dose with an Odyssey MLC block. The dose can be off by as much as a tray factor, which is typically 2% to 5%, depending on beam energy. (Z-1609-2010)

Manufacturer	Product	Class	Reason
Philips	***DigitalDiagnost*** General Radiographic Examinations and Applications; ***BuckyDiagnost*** General Radiography and Tomography Examination; ***EasyDiagnost*** Multifunctional R/F Systems	II	Device failed to display appropriate labels indicating a radiation symbol, along with required wording. (Z-0847/0849-2010)
Philips	***HeartStart MRx*** Defibrillator Monitor	II	An ECG signal processing chip may fail, causing failure to deliver therapy in AED mode or the failure to indicate poor electrical contact (very high impedance) with the patient in "Manual Defib" mode. (Z-1618-2010)
Philips	Various ***HeartStart*** Automated External Defibrillators	II	Seventeen AEDs failed production-line testing (final acceptance test). (Z-1915/1917-2010)
Philips	***Babix*** Holder	II	Potential for broken strands in the main steel cable supporting the accessory holder used with ***BuckyDiagnost*** and ***DigitalDiagnost*** X-ray systems. (Z-0021/0022-2101)
Philips	***Allura Xper*** X-ray Systems	II	Potential for table and stand not to move due to a software error. (Z-0124/0125-2011)
Philips	Various ***Allura Xper***, ***MultiDiagnost-Eleva*** and ***OmniDiagnost-Eleva*** Systems	II	A wire in the connector of the generator grid switch supervisor box might short-circuit between the 12-volt power and ground. If a short circuit occurs it may cause the system to break down. If the system fails during a critical interventional case it may cause risk to patients. (Z-0324/0327-2011)
Philips	Computed Tomography X-ray System	II	If the customer does not verify that the increment and thickness coincide with the newly selected collimation suggested by the conversion report, there is potential for a 6 mm gap to appear in axial images. (Z-0133-2011)
Philips	***Achieva*** and ***Intera*** MR systems	II	Combined use of the ***Synergy*** Flex-M/Shoulder Coil increases the chance of RF interaction and heating up of the coil. This may result in possible burns to the patient. (Z-0469-2011)
Philips	***NeuViz*** Dual Series Computed Tomography Scanner System	II	The reference lines for the image generated for a surview scan may appear in the incorrect position in the "Film" display mode. (Z-2237-2010)
Philips	Switched Internal Defibrillator Paddles	II	Paddle shock switch may fail to actuate and delay or prevent delivery of defibrillation therapy. (Z-1135-2010)
Philips	***Avalon*** Fetal Monitor	II	Potential for inaccurate ultrasound-derived fetal heart-rate readings. (Z-0549/0552-2010)
Philips	Various ***SureSigns*** Monitors and Viewers	II	Use of these devices at their maximum-volume setting may result in the premature failure of the internal speaker. (Z-0372/0374-2010)
Philips	***Eclipse*** MRI System	II	Polymeric RF connector block on the tabletop overheated and eventually ignited during scanning due to the combination of arcing of electrical components associated with the RF trap assembly located below the connector and the flame rating of the connector-block material. (Z-0780-2010)
Philips	***HeartStart*** Automated External Defibrillators	II	Potential for failure of a capacitor during use, which would prevent the AED from delivering effective defibrillation therapy when indicated. (Z-1193/1196-2010)

Manufacturer	Product	Class	Reason
Philips	***DigitalDiagnost*** X-ray System	II	When using "DICOM" print functionality, the printed images may contain data for the wrong patient. (Z-2422-2010)
Philips	***BV Pulsera*** and ***BV Endura*** Mobile X-ray Systems	II	The C-arm rotation brake does not always function properly and may not hold the C-arm position if the C-arm is not positioned in its maximum rotation, and if it is accidentally bumped by medical staff or patients. Unwanted C-arm movement may cause the C-arm to collide with a patient. (Z-2463/2464-2010)
Philips	Nuclear Magnetic Resonance Imaging System	II	The cables of the coil may become too hot and cause burns when placed too close to the patient. (Z-2461-2010)
Philips	Motorized Height Ceiling Suspensions and Motorized Height Movement (Actuator) for X-ray Systems	II	Monitor ceiling carriage may separate from the monitor ceiling suspension. (Z-2210-2010)
Philips	***Brilliance iCT*** Heavyweight Gantry Scanner	II	The gantry covers of the iCT have a latch at the base of the system that holds the cover in the closed position. If the latch comes into contact with un-insulated cabling, there is a potential that the field service engineer could receive an electrical shock. (Z-2460-2010)
Philips	***BV Pulsera*** Mobile X-ray System	II	Reliability of the stand-trolley cable may result in the loss of images on the monitor during an examination. This intermittent problem can lead to system lock-up, where no radiation is possible and images are not visible on the monitor. (Z-0140/0141-2011)
Philips	***HeartStart*** Automated External Defibrillators	II	A flash memory component was improperly relabeled by a third party. Therefore, the component could not be identified by its source, quality and date of manufacture. (Z-0483/0488-2011)
Philips	***HeartStart*** Automated External Defibrillators	II	Failure of the voltage detector may cause the AED battery to drain more rapidly than normal or make the AED unusable. (Z-0470/0473-2011)
Philips	***Easy Diagnost Eleva*** Conventional R/F System	II	Patient and image data can be exchanged when a patient is selected in the patient list and the "examination tab" is pressed with a background query running at the same time. There is a risk that the data may then be linked to the incorrect patient, which may adversely affect diagnosis and treatment. (Z-0479-2011)
Philips	***SKYLight*** Gamma Camera Gearbox Brake	II	Detector arm assembly may slide to hardware limit, potentially causing impact. (Z-0398-2011)
Philips	Monoplane and Biplane X-ray Imaging Systems	II	A lockup might occur inside the ***Velara*** generator due to intermittent shorts inside the system. The problem could only resolved by a warm- or cold-system restart. In exceptional cases the power converters of the KVmA unit in the generator are damaged and the system cannot be restarted. (Z-2448/2449-2010)
Philips	***EasyVision*** Workstation	II	Corrected software was needed to comply with 21 CFR 900.12(c)(5). (Z-0412-2011)
Philips	Anesthesia Gas Modules with Manifolds	II	The manifold seal in the water trap used on the ***IntelliVue G1***, ***IntelliVue G5*** and other anesthesia gas modules may be unintentionally removed when changing the traps. A missing seal may result in leakage and may cause incorrect monitor readings of inspiratory or expiratory gas levels. (Z-2263/2266-2010)

Manufacturer	Product	Class	Reason
Philips	***IntelliVue*** Monitors	II	Speakers on the monitors may fail, causing absence of an audible alarm and delaying patient treatment. (Z-2625/2626-2010)
Philips	***HeartStart MRx*** Defibrillator/Monitor	II	Insufficient battery power, because the user may not be alerted that no battery is installed, or that a low-battery condition exists prior to disconnecting from AC or DC power. (Z-0003-2010)
Philips	Various Health Care Products	II	Power cord prongs made by Electric-Cord Manufacturing may crack or fail. (Z-1257/1309-2010)
Physio-Control	Biphasic ***LifePak 15*** Defibrillator/Monitor	I	Potential for the device to power off and on by itself, or to power off by itself, requiring the operator to turn it back on. Or, the device doesn't turn off. (Z-1410-2010)
Physio-Control	Biphasic ***LifePak 12*** Defibrillator/Monitor	II	Affected devices contain a biphasic PCBA that may have a solder defect on the H Bridge component that could prevent the device from providing a defibrillation shock. There could be a delay in therapy or prevention of defibrillation therapy if the defibrillator was needed in a cardiac-arrest situation. (Z-0811-2010)
Physio-Control	***LifePak 20*** Defibrillator/Monitor	I	A failure on the power-supply assembly can result in either "No DC power" or "No DC or AC power." A failure of DC battery power can result in a delay of defibrillation therapy if no AC line power is available; therefore, the device will not operate. (Z-1903-2010)
Picis	***CareSuite*** Critical Care Manager	II	Under specific timing of conditions and in configuration with third-party infusion pumps, an error within the clinical application causes the manual documentation of clinical orders to be changed to an automatic update status. (Z-1252-2010)
Plexus Electronic Assembly	***Latitude*** Communicator	II	Alert conditions for a limited subset of out-of-range daily measurements related to leads may not be recognized by Model 6476 (U.S.) or Model 6468 (Europe) ***Latitude*** in-home communicators. (Z-1631-2010)
Pointe Scientific	Liquid Glucose (HEXO) Reagent Set	I	The product fails to maintain a linearity specification of 500 mg/dL. (Z-0104-2010)
Pointe Scientific	Liquid HDL (PEG) Cholesterol Reagent Set	II	There was a visible contamination of the product. (Z-0859/0860-2010)
Pointe Scientific	Uric Acid (Liquid) Reagent Set	II	A process deviation occurred during the production of the R1 component, which may affect its performance. (Z-0912/0913-2010)
Pointe Scientific	Various Calcium Reagent Sets	II	The manufacturing process for this product was not validated. (Z-1041/1043-2010)
Pointe Scientific	Various Iron Reagent Sets	II	Turbidity formation could occur, resulting in invalid test results being reported. (Z-0899/0906-2010)
Pointe Scientific	Creatinine Reagent Set; Reagent R2	II	An additional 10% picric acid was added to the R2 component during production. (Z-1035/1036-2010)
Polymer Technology Systems	PTS Panels Cholesterol Test Strips	II	The memory chip was coded with incorrect product information. (Z-0871-2010)
Polymer Technology Systems	PTS Panels Test Strips	II	The test strips appear to under-recover cholesterol, HDL and glucose. (Z-2641-2010)

Manufacturer	Product	Class	Reason
Polymer Technology Systems	PTS Panels Lipids Panel Test Strips	II	Exhibits under-recovery of all analytes. (Z-1136-2010)
Polymer Technology Systems	PTS Panels LDL Cholesterol Test Strips	III	The expiration date was extended by 20 weeks without justification. (Z-1132-2010)
Polymer Technology Systems	CHOL+HDL Panel Test Strips	III	Extended expiration date. The product expired on Feb. 12, 2009, but was labeled with an April 4, 2009, expiration date. (Z-0975-2010)
Power Medical Interventions	Various Products	II	Products were exhibiting compromised staple formation or cutting, which in some instances may result in an extended surgical time for the patient. (Z-0392/0412-2010)
Precision Medical	***PM1000*** Flow Selector	II	The on/off outlet is mislabeled. (Z-1561-2010)
Pride Mobility Products	***Jazzy Select*** Wheelchairs	II	Improper setup of the wire harness can allow wires to be pulled from their intended position and become caught under the motor-mounting bracket located under the powered wheelchair. This can cause the wire connector and/or the wire itself to be pulled or pinched, which can lead to a short- or open-circuit. (Z-2618/2619-2010)
Productos Urologos	***Medi-Vac*** Non-Conductive Suction Tube with ***Maxi-Grip*** Connectors	II	The packaging seals may not be intact, resulting in compromised sterility for the nonconductive tubing. (Z-2450/2458-2010)
PT Ciba Vision	***Air Optix***	II	The lenses inside the package do not match the prescription information for power labeled on the primary package. (Z-1706-2010)
R&D Medical Products	2-Channel Laryngeal Surface Electrode	II	Conductive glue used to attach the lead wire to the electrode caused a short-circuit in one of the channels. (Z-0798-2010)
Ram Medical	Bard Mesh Monofilament Knitted Polypropylene	I	Counterfeit product was mixed with authentic product. (Z-1647/1650-2010)
Remel	***A.C.T. II*** Sterile Pack Tube	II	Pouch may be inadequately heat-sealed, compromising sterility. (Z-1139-2010)
Remel	ERIC (Electronic RapID Compendium)	III	The database erroneously includes *Candida dubliniensis* as well as displays an incorrect temperature range as an accessory test for codes with an overlap between *Candida albicans* and *Candida dubliniensis*. (Z-0870-2010)
Remel	***Mueller Hinton*** Agar	II	Product may fail to adequately grow methicillin-resistant *Staphylococcus aureus* ATTC 43300 and *Staphylococcus aureus* ATTC 33591. (Z-0644-2010)
Remington Medical	Disposable Surgical Cable	II	The Safe Connect component may separate from the cable, causing the cable to become unplugged from the EPG. (Z-2223-2010)
Respironics	***Trilogy 100*** Ventilator	II	The battery could electrically short, resulting in a potential for fire or a thermal event. (Z-1896-2010)
Richard Wolf Medical Instruments	***Hulka*** Clip	II	The sterile pouch seal may fail to remain intact during handling, rendering the clip non-sterile. (Z-0272-2010)
Roche	***Cobas*** and ***GENT2*** Gentamicin Assays	II	A high recovery of the assay may be generated, which would lead to an underdosage of gentamicin administered to the patient. (Z-0970/0972-2010)

Manufacturer	Product	Class	Reason
Roche	Online TDM N-acetylprocainamide Reagent	II	Reagent shows an incorrect expiration date of 7/31/2011. The correct expiration date is 1/31/2011. (Z-2386-2010)
Rochester Medical	***FemSoft*** Female Urethral Insert	II	Product sterility cannot be guaranteed. If product sterility has been compromised, there is a potential for increased risk of urinary tract infection. (Z-1913-2010)
RoMedic	***EVA 450*** Patient Lift Battery Charger	II	Incorrect battery chargers were supplied with the lifts. Charger unit stops working and will not charge lift. (Z-1736-2010)
Royal Precision Plastics	***Novaplus*** Suction Canister	II	Suction canisters may crack during use. (Z-0101-2011)
Safegard Medical	***InviroSnap*** Retractable Safety Syringes	II	Syringe defects: Group 1 syringes – The plunger pull-out force was below specification. Group 2 syringes – The needle length is out-of-specification. (Z-1800-2010)
SCC Soft Computer	***SoftMic*** System	II	System may delay or omit reporting of clinically significant results, including organisms and drug sensitivities. Incomplete culture results may appear complete. (Z-0088-2011)
SCC Soft Computer	***SoftPath*** GUI System	II	Previous patient history and some QA management reports may have missing or incorrect diagnosis text. (Z-0102-2011)
SCC Soft Computer	***SoftLab*** Mic ASCII Software	I	When a test is being verified, the wrong (expired) ranges may be associated to that test result, causing an incorrect flag to be posted for that test result. (Z-0344-2011)
SCC Soft Computer	SA BASE with ***SoftLab***	II	For clients using the instrument to generate results on the Interface Menu, two different result records could be displayed under the same order and sequence numbers. This could cause incorrect results to be populated to a patient record. (Z-0364-2011)
SCC Soft Computer	***SoftID.NET*** Software	II	When using the "Cancel" functionality, if the collection list refreshes during the transaction and changes the position of the patient on the list, the wrong patient order can be cancelled. (Z-0360-2011)
SCC Soft Computer	***SoftBank*** Software with ***SoftReports***	II	For clients generating patient history reports using the "Patient>Reports>Batch Reports>History Report" option in ***SoftBank*** with ***SoftReports*** activated for patient reports, when the report is generated for more than one patient, all of the results for the qualified patients are displayed under each patient's header. (Z-0362-2011)
SCC Soft Computer	***SoftLab*** GUI Software	II	Clients using "Patient Maintenance" to perform "Moves of Stays" may send the wrong billing number during an ADT update to ***SoftWeb***, ***SoftPath*** or ***SoftMedia***. The wrong billing number can come from a different patient in "Order Entry." Only "Moves of Stays" is affected. (Z-0365-2011)
Sedecal	***Hydradjust*** I.V. DR Urological Table Sedecal Generator	II	Generator may fail and produce smoke. The failure modes are located in different parts of the generator and will lead to the generator becoming inoperative. (Z-1904-2010)
Seisa Medical	***ABC Bend-A-Beam*** Handpiece; ***ABC*** Handswitching Probe	II	The internal electrode can protrude in front of ceramic insulator at the tip of the ABC Handpiece used with Conmed electrosurgical units. (Z-2276/2282-2010)

Manufacturer	Product	Class	Reason
SenDx Medical	ABL 80 CO-OX System	II	A software error can occur if the analyzer is set to automatically upload patient records to ***Radiance*** or an HIS/LIS system. This can result in the reporting of incorrect results for one or more CO-OX derived parameters. Incorrect results can be displayed on the screen and the sample printout. (Z-0150-2010)
Sensidyne	Oxygen Sensor	II	Sensor causes the oxygen monitor to prematurely display a low-sensor warning, which indicates an early maintenance requirement for the instrument. This may result in interrupted treatment. (Z-0585-2010)
Sgarlato Med	Sgarlato Labs GAIT (Great Toe Implant Technique) Implant	II	Products with an expiration date of August 2009 were labeled with an expiration date of May 2013. Additionally, the outer packages were labeled with an incorrect lot number. (Z-2173-2010)
Shenzhen Mindray Bio-Medical Electronics	Various ***SmarTemp*** Probe Covers	II	Probe covers may contain microscopic holes in the molded seam that would allow liquids or body fluids inside the cover and potentially contaminate the temperature probe. (Z-1396/1398-2010)
Shinamerica	***Live Better*** Insulin Syringes	II	Product mislabeled. (Z-1217-2010)
Shirakawa Olympus	Camera Heads	II	Endoscopic body-type camera heads labeled as cardiac-type. (Z-2642-2010)
Siemens	***Axiom Artis*** Systems with Motor Controller Unit	II	Sporadic malfunctions caused by tolerances on electronic parts that might increase during the lifetime of the system. (Z-1732-2010)
Siemens	***Axiom Artis*** MP/Artis dMP and ***Artis Zee*** Multipurpose	II	C-arm gearbox can become damaged. If the gearbox is damaged, the C-arm may tilt away when being repositioned and collide with nearby objects in its range of motion. (Z-2233-2010)
Siemens	550 TxT Patient Table	II	An increase in voltage may cause a short-circuit of a power transistor that may cause a smoldering and smoking effect of the electrical wiring, and also an unexpected lowering of the table. Both issues present the potential for injury to a patient or the operator. (Z-0166-2011)
Siemens	***Artiste MV***	II	The robotic lift armature shaft may break and allow the flat panel positioner with the digital flat panel imager to fall into the flat panel cradle. If the positioner is over a patient, there is a potential for injury. (Z-0449-2011)
Siemens	***Axiom Artis*** Systems with ***Perivision*** Functionality	II	Sporadic system crash while ***Perivision*** is performed. (Z-0144-2011)
Siemens	***Dimension*** Tacrolimus Flex Reagent Cartridge	II	Low patient sample recovery results in all affected lots, with possibility of inappropriate increase in tacrolimus dosage based on false-low result. (Z-2407-2010)
Siemens	***Dimension Vista*** System BUN Flex Reagent Cartridge	II	Patient sample BUN results reported may be higher or lower than the actual level. (Z-1017-2010)
Siemens	***Immulite*** Chemiluminescent Substrate Modules	II	Substrate lots have shown a tendency to introduce a shift in both control and patient results with multiple methods. (Z-1891-2010)
Siemens	***Dimension Vista*** LOCI Reaction Vessels	III	Vessel pick-up errors and vessel jams when the vessel is being loaded. The error halts the instrument and disrupts processing. Vessel flange is thin. (Z-2117-2010)

Manufacturer	Product	Class	Reason
Siemens	***Dimension*** IBCT Flex Reagent Cartridge	III	Test produces falsely elevated IBCT results and abnormal reaction test report messages on heparinized plasma samples. (Z-2385-2010)
Siemens	***Dimension Vista*** Intelligent Laboratory System	II	Defective batteries may overheat and cause a strong sulfuric odor to be released, and a corrosive sulfuric acid solution leak to occur. (Z-2423-2010)
Siemens	***Dimension Vista*** V-LYTE Standard A	II	High potassium content results in the potential for low potassium recovery for dilution check, QC and patient samples when run on the ***Dimension Vista*** System. (Z-0139-2011)
Siemens	***EasyLink*** Informatics Systems	II	Does not operate as intended. (Z-0121-2011)
Siemens	Various ***Dimension Flex*** Reagent Cartridges	II	Some cartridges have sub-optimal seal of the lidstock that can cause rupture of the package at high elevations, causing the cartridge to leak. Use of leaking cartridges may result in inaccurate test results. (Z-0458/0461-2011)
Siemens	***Dimension Vista*** CHEM 3 Calibrator	II	Patient results are depressed. (Z-1535-2010)
Siemens	***Dimension Vista*** ECREA Flex Reagent Cartridge	II	Test results may be falsely elevated or depressed. (Z-2419-2010)
Siemens	***Artiste Syngo*** RT Therapist	II	A failed data transfer is possible that may result in data not being recorded in the interfaced system. (Z-0121-2010)
Siemens	***Axiom Artis*** Systems	II	Communication problems can occur, which may result in unavailability of bypass fluoro. (Z-1312-2010)
Siemens	***Axiom Artis*** Systems	II	Sporadic malfunctions are caused by tolerances on electronic parts that might increase during the lifetime of the system. (Z-1732-2010)
Siemens	***Syngo*** Imaging Systems	II	There is a potential malfunction and hazard to patients when using ***Syngo*** imaging systems in combination with an RIS that is violating the DICOM standard by creating non-unique study instance UIDs. (Z-1892-2010)
Siemens	***Syngo*** Imaging XS	II	Images can be overwritten. (Z-1423-2010)
Siemens	***Biograph*** Devices	II	If the device is modified to operate in the tilted position, the telescoping support mechanism will not engage properly. (Z-0162/0164-2010)
Sigma	***Spectrum*** Volumetric Infusion Pump	I	Pumps have the potential to fail, causing inaccurate flow conditions during use. These conditions range from back-flow to free-flow, which could result in over-infusion. (Z-0146-2011)
Sigma-Aldrich	Histopaque-1077	II	Product was contaminated with *Pseudomonas mendocina*. (Z-0974-2010)
Sigma-Aldrich	Histopaque-1077; Histopaque-1119	II	Instructions for use was revised to recommend sterile filtering of the product under certain circumstances. (Z-0976/0977-2010)
Smith & Nephew	***Journey*** Uni Tibial Baseplate Insert	II	Baseplates may break in situ. If a breakage occurs, the broken baseplate must be revised and/or changed. If left unrevised, a broken base could lead to instability and premature wear of the construct. (Z-0924/0967-2010)
Smith & Nephew	***Genesis II*** Tibial Drill Guide	II	Markings for the drill guides are on the incorrect side. (Z-1900-2010)

Manufacturer	Product	Class	Reason
Smith & Nephew	***Peri-Loc***	II	Inner packaging of the sterile product was not sealed. (Z-2314-2010)
Smith & Nephew	Cerclage Wire	II	Plastic trays that encase these products have burrs on the hinged packaging, which can puncture the single-barrier sterile pouch, compromising sterility. (Z-2197/2199-2010)
Smith & Nephew	***Aimer*** Endofemoral	II	Tip may separate due to failure of the soldered joint. (Z-0040/0048-2011)
Smith & Nephew	R3 22 MM I.D.	II	The femoral head may pop out of the liner intraoperatively. (Z-0079/0086-2011)
Smith & Nephew	***Trigen Sureshot*** Distal Targeting System	II	Software has been found to provide erroneous targeting. (Z-0411-2011)
Smith & Nephew	***Fast Fix 360*** Needle Delivery System	II	System may not allow the T-2 anchor to advance for implantation. (Z-0419/0421-2011)
Smiths Medical	***Medfusion*** Syringe Infusion Pumps	II	Pumps with obsolete software may continue to run past the set volume limit. This can result in over-delivery if the syringe is overfilled. (Z-2121-2010)
Smiths Medical	AC Power Cords	II	Potential for the power cord's prongs, made by Electri-Cord Manufacturing**,** to crack and fail at/or inside the plug. (Z-1082-2010)
Smiths Medical	***CADD-Legacy 1*** Ambulatory Infusion Pump	II	Pump was shipped without documentation that required accuracy testing had been performed during the manufacturing process. If the pump did not go through accuracy testing and does not meet accuracy specifications, there is a potential for over- or under-delivery. (Z-1235-2010)
Smiths Medical	***Medfusion*** Syringe Infusion Pumps	II	There has been an increased trend in reports of "Motor Not Running" (MNR) and "Motor Rate Error" (MRE) alarm-message events. This is likely to cause an interruption or delay in therapy for the patient. (Z-0650/0651-2010)
Smiths Medical	Power Cords	II	According to FDA, two medical device manufactures have reported incidents of sparking, charring and fires from power cords made by Electri-Cord Manufacturing. (Z-0918/0920-2010)
Solafeet	Foot Portable Tanners	II	Product failed to have a label that contained a recommended exposure schedule, and the operator's manual provided inadequate instructions for use. (Z-0608-2010)
SonaMed	***Clarity*** System II	II	There is insufficient evidence to support any claims for safety and efficacy. (Z-2165-2010)
Sonosite	***Tee*** Transducer	II	The transducer, when connected to a Sonosite ***M-Turbo*** ultrasound system, may exhibit erratic operation of the "Scanplane Orientation Indicator" on the system display. The indicator may move erratically and not accurately represent the orientation of the ***Tee*** transducer array. (Z-2191-2010)
Sonosite	***PowerPark*** System	II	System has the potential for loss of power at the corresponding wall outlet and/or circuit due to poor alignment. (Z-2116-2010)
Sonosite	***ARM*** Software	III	Software on the ***NanoMaxx*** ultrasound system results in errors when the "Print" command is selected. As a result, the displayed MI or TI values may be incorrect. (Z-0478-2011)
Sorin Group	***Paradym*** CRT-D Devices	II	Devices have a software anomaly that causes the device to lose the ability to sense/pace and deliver further therapy. (Z-2579-2010)

Manufacturer	Product	Class	Reason
Sorin Group	***OptiPack***	II	Defective product packaging may compromise product sterility. (Z-0370/0391-2011)
Sorin Group	***Revolution*** Blood Pumps	II	A weakness in the plastic packaging tray could cause the tray to crack, compromising product sterility. (Z-0192/0193-2010)
Sorin Group	Various EVH Vessel-Clamping Devices	II	Device may break during use. (Z-0624/0630-2010)
Southeastern Technology	***Dart-Fire*** Cannulated Driver Star No. 8	II	After autoclaving, the epoxy identifier (colored) band bled, and there is concern that it may flake. (Z-2470-2010)
Spectranetics	***QuickCat*** Extraction Catheter	II	Guide wire lumen may be occluded, preventing guide wire insertion into the catheter. (Z-2190-2010)
SpineMatrix	Lumbar Matrix Scan	II	A full design review of the system was conducted. The audit revealed numerous design verification tests that either did not pass or did not meet the design input requirements. (Z-1935-2010)
Spire Biomedical	Various STD Kits	II	There is a possibility that the catheter tubing could separate from the hub/bifurcation of the device. If this occurs, bleeding is the primary clinical complication likely to result from catheter tubing/hub separation. A second potential clinical complication is air embolism, particularly for the segment of the patient population that develops negative central venous pressure during normal respiration. (Z-0288/0335-2010)
St. Jude Medical	***Epicor UltraWand*** LP Handheld Ablation Device	II	Overheating of cardiac tissue is caused by inadequate cooling. (Z-1780-2010)
St. Jude Medical	***Engage TR*** Introducer	I	Introducers have the potential for a partial or complete separation of the shaft (sheath) from the hub, or a material break in the hub assembly just distal to the hemostasis seal. If either of these were to occur during use, it is likely that fluids would leak around the introducer hub and strain relief. (Z-2178/2182-2010)
Stanley Security Solutions	***Tabs*** Professional Monitor	II	Product might not indicate low-battery alarms or exit alarms when powered by a DC power supply. (Z-1944/1947-2010)
Starion Instruments	Thermal Ligating Shears	II	Shears may turn on and remain on without the finger-button being depressed. The devices may also work intermittently, incorrectly indicating that the device is turned on. (Z-2239-2010)
StatSpin	***Express 4*** Horizontal Centrifuge	I	The centrifuge shield micro-switch failed due to damage, and the unit opened and ejected pieces. (Z-0807-2010)
StelKast	***Unicondylar*** Knee Femoral Component	II	Incorrect size markings on component. (Z-0371-2010)
Steris	***Harmony Lux Advantage*** and ***Classic LA Surgical*** Lighting and Visualization Systems	II	Premature bulb failure. (Z-1218/1220-2010)
Steris	Various Surgical Tables	II	Manifold assemblies were manufactured by a supplier with incorrect washers and springs in the valves of the manifold. (Z-1941-2010)

Manufacturer	Product	Class	Reason
Stryker	***Visum*** LED Surgical Lights; Equipment Delivery System; ***Visum*** Halogen Surgical Lights; ***SwitchPoint*** Element Control System; ***SwitchPoint Infinity*** Control System; Ceiling Suspensions	II	Installation records are incomplete. (Z-1640/1645-2010)
Stryker	SDC HD and HDi Units	II	Video device is not able to assign the correct time/date stamp. (Z-1590-2010)
Stryker	***Crossfire*** Console	II	RF energy or powered shaver handpieces may continue to operate when not intended when used with the ***iSwitch*** wireless foot switch. (Z-2193-2010)
Stryker	Scope Warmer	II	Outer packaging seals have inconsistencies that have resulted in compromised seals, and may result in compromised sterility. (Z-2622-2010)
Stryker	***Triathlon*** Total Stabilizer Femoral Component	II	Components may have been damaged during manufacturing, possibly preventing the assembly of a stem extension. (Z-0757/0761-2010)
Stryker	Reamer T-Handle	II	T-handles have the potential to not engage and not attach to the reamer properly. (Z-0793/0794-2010)
Stryker	***Scorpio PS*** Femoral Waffle and Lfit	II	Package mislabeled. (Z-0795-2010)
Stryker	***Trident*** Acetabular Hip System Polyethylene Inserts; ***Triathlon X3*** UHMWPE Tibial	II	Packaging problems. (Z-0909/0911-2010)
Stryker	Distal Centralizer	II	Labels have incorrectly printed manufacture dates, and thus incorrect expiration dates on the product label. (Z-1601-2010)
Stryker	***Passport*** A.R. Knee Instrumentation Anterior Skim Guide	II	One of the two posts on the anterior resection guide could disassociate from the main body of the part, which has been determined to be caused by a fracture weld. (Z-2120-2010)
Stryker	***Passport*** A.R. Knee Instrumentation Distal Guide Stand	II	There is the potential for the posts on the distal resection guide stand to disassociate from the main body part. (Z-2118-2010)
Stryker	***X-Celerate*** Instrumentation Punch Thru Tibial Baseplate	II	The locating pins on the baseplates could break or disassociate from the main body of the instrument. (Z-2119-2010)
Stryker	***Scorpio/NRG 4-in-1*** Cutting Block	II	The cutting blocks have fractured on impaction during surgery. (Z-0049/0057-2011)
Stryker	Various Sizes of ***Scorpio*** Ceramic Guides and ***Duracon*** Ceramic Cutting Blocks	II	The ceramic guide rails may fracture and displace from the block. (Z-1574/1589-2010)
Stryker	***Accolade*** Distal Centralizer	II	Product incorrectly labeled. (Z-1593/1594-2010)
Stryker	Guardian Services Software	II	Stryker determined that Guardian Services does not contain 100% data backup for 12 ***OfficePACS*** Power customers on a daily basis. (Z-0134-2010)

Manufacturer	Product	Class	Reason
Stryker	MIS Bur	II	The bur may fracture, resulting in fragments within the surgical site, injury to the patient or surgical team, or both. (Z-0595/0599-2010)
Stryker	***Navigation System II*** CART and PC SPC-1 Assembly	I	Multiple software-related malfunctions may occur. The device may suddenly stop working, the screen may freeze, the screen may update very slowly, the unit may not respond to user input, or the unit may respond to the user very slowly. (Z-0122/0123-2010)
Stryker	***Atlas***, ***M-Series*** and ***Renaissance*** Series Stretchers Power Cord Kits	II	The retractable cord stretchers were fitted with power cords, made by Electri-Cord Manufacturing, whose prongs have the potential to fracture inside the molded section of the plug, causing melting and charring. (Z-2183/2187-2010)
Stryker	***Epic II*** and ***Zoom*** Critical Care Beds	II	The Fowler mechanism may malfunction, preventing it from being lowered into a flat position. (Z-2586/2587-2010)
Stryker	Various Types of CBCII ***ConstaVac*** Blood Conservation Systems/Kits	II	The product may not be sterile due to package not being intact. (Z-0719/0743-2010)
Stryker	Various ***PainPump*** Devices	II	All failures lead to the patient receiving less medication than intended. Certain lots of the pain pump have a high failure rate associated with a cracked port housing, which leads to internal or external leaks. (Z-2591/2594-2010)
Stryker	Various ***PainPump*** Devices	II	The indication for use has been changed to remove site-specific pain management. The firm has revised the warning to not use the pump around joint spaces. A warning has been added regarding the use of the pump with anticoagulants in epidural applications. A special reminder to users to always evaluate potential risks when using anticoagulants in epidural applications. (Z-0096/0098-2011)
Stryker	***AVS TL*** Trial Spacers	II	The distal end of the trial spacer may break during the trialing step of the ***AVS TL*** procedure. (Z-1957/1968-2010)
Stryker	***XIA 3*** Polyaxial Screw	II	The screws were anodized turquoise instead of fuchsia. The turquoise color is reserved for a different size of screw. (Z-0823-2010)
Stryker	Literature for Implant Extraction Set	II	Literature did not include the design change to a smaller cannulation diameter. (Z-1443-2010)
Stryker	Depth Gauge	II	Gauges have a 5-scale marking instead of the required 4-scale marking. (Z-0796-2010)
Stryker	***T2*** Ankle Arthrodesis Nail	II	There is the potential for damage to the sterile packaging of the product during transport. (Z-0841/0846-2010)
Stryker	Long Nail Kit	II	The nail has no thread for the set screw, hindering insertion. (Z-2340-2010)
Stryker	Trial Cup Holder	II	Cup holder may not have been assembled correctly. (Z-1201-2010)
Sybron Dental Specialties	***Sealapex Express***	II	There is the presence of crystals in the catalyst. This crystallization may affect proper canal filling by preventing Gutta Percha Points from reaching the bottom of the root canal, which may lead to an inadequate seal. (Z-0917-2010)

Manufacturer	Product	Class	Reason
Sybron Dental Specialties	***Herculite Ultra***	III	There was a mistake in the directions for use. (Z-0916-2010)
Synovis Surgical Inovation	PSD Gel	II	There is a potential for small defects in the PSD gel tube pouch, which may compromise the sterility of the outside of the gel tube. (Z-2447-2010)
Synthes	***TI Synex II*** Central Body	I	There may be a loss of device height. (Z-0108/0118-2010)
Synthes	LCP Periarticular Proximal Humerus Plates	II	Screw can pass through plate hole. (Z-0309-2011)
Synthes	Screw Manipulation Forceps; Bending Pliers; Plate Holding Forceps; Matrixmandible Sagittal Split PL; Drill Bit Stryker J-Latch	II	The customized plate instruments do not have a cleared premarket notification. (Z-0075/0082-2010)
Synthes	In Situ Bender/Cutter	II	There is the potential for the bender/cutter attachment to continue heating after release of the power button. There is potential for patient and/or staff injury if continuous heating is unrecognized. (Z-0825-2010)
Synthes	Medullary Tubes	II	After repeated sterilizations, product may become discolored and break, including while in the medullary canal. (Z-1804-2010)
Synthes	***SynFix-LR*** Spinal Implant System	II	There is a potential for the implant holder tip to break off in the implant, which poses a potential risk to the patient. (Z-2583-2010)
Synthes	Ti Solid Humeral Nail	II	Potential compatibility issue. (Z-1548/1549-2010)
TAG Medical	***Tornier Arthro*** Tunneler	II	Device failed to deploy the distal loop. (Z-0656-2010)
Techniko	***Unilect*** ECG Electrodes	II	In an emergency situation where defibrillation is necessary and electrodes are already in use, the electrodes may malfunction and incorrectly report lack of cardiac activity. (Z-1431-2010)
Teleflex Medical	Hudson RCI ***ConchaTherm Neptune*** Heated Humidifier	II	When turned on, the ***Neptune*** heater may cause an artifact on the patient's heart monitor. (Z-1040-2010)
Teleflex Medical	***Deknatel Bondek Plus*** Polyglycolic Absorbable Surgical Sutures	II	The products inside the box are of a different catalog number than labeled on the outer box. (Z-2286/2287-2010)
Teleflex Medical	***Weck*** IMA/ENT Blade Electrode	II	Complaints were received regarding peeling and melting of the insulation of the cautery tip of the blade electrodes. (Z-2584-2010)
Teleflex Medical	Hudson RCI ***AQUA+ Flex***	I	The patient-end of the connector on the flex tube may not fit securely within the endotracheal tube connector, thereby disconnecting from the endotracheal tube. A disconnect in ventilator-dependent patients without prompt response to the alarm could lead to hypoxia, organ failure or cardio-respiratory arrest. (Z-1634-2010)
Teleflex Medical	Hudson RCI One-Way Valve	II	Product Code 1664 was incorrectly packaged as Product Code 1665. If the red arrows are not followed, the valve may be placed in the circuit in the wrong orientation for gas flow. Severe restriction of patient inspiration or expiration will occur. (Z-0652-2010)

Manufacturer	Product	Class	Reason
Terumo Cardiovascular Systems	Various ***Sarns*** Cardioplegia Sets; Various Cardiovascular Procedure Kits	II	Vent port may be occluded and prevent delivery of priming fluid. (Z-2610/2617-2010)
Terumo Cardiovascular Systems	***Sarns*** Centrifugal Pump	II	The tubing-to-pump connection in a medical device used in surgical procedures may disengage, resulting in blood loss. (Z-0544/0545-2010)
Terumo Cardiovascular Systems	***Sarns*** Centrifugal Pump	II	Medical device component may malfunction and require user intervention during surgical bypass procedures. (Z-2606-2010)
Terumo Cardiovascular Systems	***Advanced Perfusion System 1***	II	The design document states that the oxygen sensor would operate for 300,000 hours, but the supplier of the oxygen sensor indicated that it has a 100,000-hour warranty. The oxygen sensor is a consumable part that slowly depletes over time. At the end of its service life, a depleted oxygen sensor results in a gas system calibration failure or a message to the user prompting service for the gas system. If the user does not recognize that the gas system has failed calibration, and attempts to use the system normally, the FiO2 readings may be inaccurate. (Z-2480/2481-2010)
Terumo Cardiovascular Systems	Air Bubble Detection Cable Assembly	II	Malfunction causes a false-air alarm or a check-sensor message during system setup. In some instances, users were not able to reset the alarm to allow for further air-bubble detection. (Z-0024-2011)
Terumo Cardiovascular Systems	Various Cardiovascular Procedure Kits	II	Vent port maybe occluded and prevent delivery of fluid. (Z-2149/2163-2010)
Terumo Cardiovascular Systems	***Sarns 8000*** Roller Pump	II	The roller pumps may fail, resulting in a persistent pump stop. (Z-0562/0563-2011)
TFX Engineering	***Imager II*** Catheters	II	The sterile barrier in the packaging that contains the catheter may be breached. The breach of sterility could lead to a contamination of the device with a subsequent transfer of infectious agents to the patient. (Z-0336/0337-2010)
Theken Spine	***Manta Ray*** Anterior Cervical Plate System	II	Screws were backing out of the device during surgical procedures. (Z-0087-2011)
Theken Spine	Bone Void Filler	II	A separation occurred between the flowable carrier and the B-TriCalcium Phosphate within some of the product syringes. (Z-0169-2011)
Therakos	***CellEx*** Photopheresis System Procedural Kits	II	Higher-than-normal blood leaks. (Z-1654-2010)
Thermo Fisher Scientific	***GasPak EZ*** Large Incubation Container	II	In vitro diagnostic reagent containers may be defective and could cause incorrect test results in patient samples. (Z-0480-2011)
Thomas Medical Products	***Safesheath*** Coronary Sinus Guide Hemostatic Tear Away Introducer System	I	Radiopaque sheath tip may fracture. (Z-0661-2010)
Thoratec	***HeartMate II*** System Controller	II	Product may malfunction because of bent pins or broken wires in power-cord connection. (Z-0058-2011)

Manufacturer	Product	Class	Reason
TomoTherapy	***Hi-Art*** System	II	In some cases, the patient's diagnostic CT image is narrower than the Hi-Art radiotherapy couch image. (Z-2115-2010)
Toshiba Medical Systems	***Aquilion One*** Whole Body X-ray CT Scanner	II	Scanning cannot be performed at the appropriate time of constant enhancement, and clinically useful images may not be obtained. (Z-0907-2010)
Toshiba Medical Systems	***Aplio Artida*** System	II	When an image is transferred from this system in "DICOM" transfer, and a measurement is performed on a Doppler image in the DICOM viewer, measured values such as VTI (Velocity Time Integral) and PI/RI (Pulsatility Index I Resistance Index) will frequently be displayed incorrectly. (Z-1955-2010)
Toshiba Medical Systems	***Aplio*** Devices	II	Product does not meet the safety standard requirements. (Z-1171/1173-2010)
Toshiba Medical Systems	***Aquilion ONE*** CT System	II	Scan may stop. (Z-2339-2010)
Toshiba Medical Systems	Endocavitary Transducer	II	Incorrect sweep-direction setting. (Z-1997-2010)
TransEnterix	***Spider*** Flex Monopolar Hook	II	The hook end effecter from a monopolar device may become dislodged and fall into the patient when in use during laparoscopic surgery. Retrieval from the patient may involve extended anesthesia time. (Z-2465-2010)
Triple G Systems Group	***Centricity*** Laboratory Instrument Interface Software	II	Instrument may incorrectly report the result of an antimicrobial sensitivity test. (Z-0123-2011)
Troy Innovative Instruments	Modified Depth Gauges	II	The print for modified CSS depth gauges has an inaccurate definition of the etched screw length. The error results in a length reading that is longer than the actual length of the buried guide wire segment, and even longer than the design intention readings. Use of the affected device may result in soft tissue, vascular or nerve damage, or encroachment of an articular surface. (Z-0466/0468-2011)
U.S. Machine and Tool	***VP 2000*** Processor Heated Reagent Basins	II	The basins crack along the bottom seam, have non-uniform coating of interior corners, may be warped, and some may have incorrect dimensions. (Z-2313-2010)
Unique Media	***Image Consultant*** Software	II	Software not validated. (Z-1176-2010)
Unomedical	***Neutralect*** Diathermy Cable	II	Boxes mislabeled. (Z-1142-2010)
Urologix	Various CTC Advance Catheters	II	The expiration date is printed as "2012-12" when it should read "2011-12." Only the individual product label contains the incorrect date; the kit-box label is correct. (Z-1174-2010)
USSC	***Auto Suture ProTack*** Fixation	II	Fixation device may fail to fire and staple. (Z-1157-2010)
Varian Medical Systems	***Eclipse*** Treatment Planning System	II	When preparing a treatment plan involving a split, the device may calculate excessive or insufficient monitor units for the treatment plan. (Z-1412-2010)

Manufacturer	Product	Class	Reason
Varian Medical Systems	***TrueBeam*** Devices	II	Due to a software anomaly, guidance-based couch-shift values may not be applied as expected when the operator selects "Apply Shift" and presses the "Motion Enable" buttons. This can result in the actual patient position differing from the position indicated by the imaging application, affecting position accuracy and precision. (Z-0106-2011)
Vascular Solutions	***Langston*** Dual Lumen Catheters	II	Pouches containing catheters were missing a seal, posing a risk of product contamination. It is possible that a compromised sterile barrier could go unnoticed and the contaminated product could be used on a patient. Use of contaminated product could lead to an infection possibly requiring medication, hospitalization and/or medical intervention. (Z-2608-2010)
Vascular Solutions	***Pronto-Short*** Extraction Catheter	II	Three device lots were manufactured and labeled with an expiration date that is inconsistent with the expiration of the included guide wire component. The guide wire is sterilized separately and had an expiration date of October 31, 2009. (Z-0547-2010)
Ventana Medical Systems	***Pathway*** Anti-Her-2/NEU Rabbit Monoclonal Primary Antibody	II	Staining inconsistencies. (Z-1146-2010)
Ventus Medical	***Provent*** Nasal Cannula	III	The catalog number printed on two nasal cannula diagnostic kits was different than the catalog number printed on the bulk pack shipper box and the other nasal cannula kits in the same shipper. (Z-2435-2010)
Verathon	***ScanPoint*** Docking Station	II	Incorrect programming. (Z-0143-2011)
Verathon	***BVI 9600*** Bladder Volume Instrument; ***AortaScan*** AMI 9700; ***BladderScan*** BVM 9500	II	Devices may experience the loss of a factory-installed software configuration file, which results in the loss of the aorta measurement function (Z-0003/0005-2011)
Veridex	***CellTracks*** Auto Prep System	II	Complaints of patient sample carryover. (Z-2175-2010)
Veridex	***CellSearch*** Circulating Tumor Cell Kit	II	Reagent bottles were incorrectly placed, or duplicate bottles were placed, within the reagent tray of the kit. (Z-0819-2010)
Vintage Pharmaceuticals	***AccuSure***	II	Needles become dislodged from the barrels. (Z-0569/0576-2010)
Vistakon	***Acuvue Oasys*** Contact Lenses	III	Lenses may be mislabeled. (Z-2445-2010)
Vital Images	***Vitrea Enterprise*** Software	II	Incorrect measurements may result from software use. (Z-1600-2010)
Vital Signs	***enFlow*** Disposable I.V. Fluid/Blood Warmer Cartridge	II	Cartridge's male luer-lock fitting may be oversized and may not fit properly with standard female luer fittings. (Z-2380-2010)
Volcano	***s5/s5i*** Imaging System	II	Software defect results in improper image brightness, which may result in introduction of artifacts, which may cause misclassification of results and affect classification of tissue types. This may result in misdiagnosis and inappropriate treatment. (Z-0168-2011)
WalkMed	***Triton*** Pole Mount Infusion Pump	I	Pump door may be in a near-shut position, but unlatched, and the "Door Open" alarm may not sound. (Z-0307-2011)

Manufacturer	Product	Class	Reason
Wally's Natural Products	Ear Candles	II	Product is an unapproved medical device. Use as directed may result in accidental damage to the eardrum, leading to injuries up to loss of hearing. (Z-2487-2010)
Westmed	***BagEasy*** Manual Resuscitation Devices	I	There is a potential for disconnection at the patient port retention ring assembly. (Z-2332/2333-2010)
Wilden	***Excyte*** Slider Barcode Tube Adapter	III	The tube may fall out or separate from the slider adapter. (Z-1816-2010)
Winco	***Care Cliner*** Chair	II	Chair has malfunctioning axles that become loose from the caster assembly. (Z-0147-2011)
Wright Medical Technology	***Advance*** Duramer Tibial Insert	II	The left medial pivot and right medial pivot inserts were comingled. (Z-1636/1637-2010)
Wright Medical Technology	Claw Hex Screw Charlotte F&A System	II	Screws were incorrectly packaged. (Z-2188-2010)
Wright Medical Technology	***Advance*** Tibial Wedge Augment	II	The product contained screws with the incorrect length. (Z-1215-2010)
Wright Medical Technology	***Rayhack*** Drill Guide Angled	II	Drill guides from two lots may not seat properly on the compression block. (Z-1779-2010)
Wright Medical Technology	***Dynasty*** A-Class Poly Liner	II	The inner- and outer-product packaging was missing the following information: shelf life, translations, manufacturing date and CE marking. It also listed an incorrect sterilization method. (Z-2212-2010)
Yokogawa Medical Systems	***LightSpeed*** and ***BrightSpeed*** Scanner Systems	II	A potential set of circumstances could cause X-ray continuation during an unexpected table stop. (Z-0368/0369-2011)
Yokogawa Medical Systems	Signa ***OpenSpeed*** and ***Ovation***	II	If the lateral table adjustment crank handle breaks off, it has sufficient attractive force to the magnet and may result in patient injury (Z-0425/0426-2011)
Zap Lasers	***SoftLase Pro*** Dental Lasers	II	Lasers are in need of compliance upgrades due to lack of a remote interlock connector, an emission delay, user-guide labels and locations, and calibration procedures and schedule. (Z-0587-2010)
Zimmer	Trabecular Metal Shoulder	II	Devices may possess a taper that will not mate with the humeral head. (Z-0177/0178-2010)
Zimmer	***NextGen Knee Gender Solution*** CR-Flex Femoral Component	II	The package should contain the left knee component, but it actually contains the right knee component. Delay in completing surgery may result, and a new or different implant may need to be identified. (Z-0915-2010)
Zimmer	***NexGen Complete Knee Solution*** Tibial Tray	II	The titanium portion of the implant may separate from the trabecular metal material. (Z-1064-2010)
Zimmer	ITST Intertrochanteric/ Subtrochanteric Fixation Locking Bolt Extractor	II	Instruments were manufactured with the incorrect grade of steel, increasing the potential for fracture during use. (Z-2289-2010)
Zimmer	Various Sizes of ***NexGen Complete Knee Solution***	II	The implanted device may loosen, requiring revision surgery. (Z-2408/2418-2010)

Manufacturer	Product	Class	Reason
Zimmer	***Continuum*** Acetabular Systems Shell Inserter Adapter	II	The firm has received reports of users encountering difficulties in usage leading to surgical delays or minor damage to a threaded surface of the shell implant. (Z-0071/0072-2011)
Zimmer	Trabecular Metal Modular Acetabular System	II	The threads on the device were not completely machined and therefore would not mate with the corresponding cup positioner/shell inserter. (Z-0060-2011)
Zimmer	Drill Stop Kit	II	The instructions for use contain pre-vacuum sterilization instructions that may lead to compromised sterility at the lid-kit interface location. (Z-0444-2011)
Zimmer	***NexGen Complete Knee Solution*** LPS Femoral Component	II	Products exhibit a nonconforming internal CAM radius. The condition is intermittent and not all devices have nonconforming geometry. (Z-0528/0536-2011)
Zimmer	Various ***Reconstruction*** Systems	II	Instruments were manufactured using the wrong grade of material. As manufactured, the instruments are more brittle, increasing the potential for fracture. (Z-0493/0501-2011)
Zimmer	***Versys*** Hip System Femoral Head	II	There is a potential for a package to be mislabeled. In addition, the patient record label may be incorrect. (Z-2290/2291-2010)
Zimmer	***Pathfinder*** End Screw Extender Sleeve	II	The tip sleeve has fractured during use. In some cases, this instrument fracture led to surgical delay or additional surgical steps necessary to remove the fragments of the broken tip. (Z-0075-2011)
Zimmer	Trabecular Metal Femoral Cone Augment	II	There is a potential for the packages to be mislabeled. Specifically, the left femoral cone augment component may be labeled as "right," and the right femoral cone augment component may be labeled as "left." (Z-2439/2440-2010)
Zoll	***E Series*** Defibrillator/ Pacemaker/ Monitors	II	Device issued a "Shock Advised" message but failed to autocharge the defibrillator. (Z-1547-2010)

FDA Warning Letters

The following chart lists medical device-related warning letters released by FDA from Jan. 11 through Feb. 7. If an inspection led to the warning letter, the location of the inspected facility and dates of inspection are noted; otherwise, the location of the warning letter recipient is listed.

Description	Summary
Access Bio Inc. Warning letter date: Dec. 22, 2010 Location: Somerset, N.J. Inspection dates: Aug. 4-31, 2010	Manufacturer of in vitro diagnostic test kits, including the ***CareStart*** HIV, Syphilis, Malaria and HCV test kits, cited for QS and pre-market reg violations. The firm failed to establish and maintain procedures for device history records; for example, the company didn't maintain copies of labels used for each lot or batch that included the lot number or expiration date. Documents were not controlled. Purchasing control procedures weren't established and maintained; for example, suppliers were not listed on an approved supplier list. Finally, the firm was selling its test kits without pre-market approval or pre-market clearance from FDA. [Issued by New Jersey District Office]
Alphatec Spine Inc. Warning letter date: Jan. 11, 2011 Location: Carlsbad, Calif.	Manufacturer of the ***Zodiac DynaMo*** and ***Isobar*** Semi-Rigid Spinal Systems, and the Isobar semi-rigid dual dampener was ordered by FDA in October 2009 to conduct post-market surveillance of the devices. However, the firm failed to comply and did not revise its post-market surveillance submissions to address FDA's concerns. [Issued by CDRH]
Costumes For Your Eyes Warning letter date: Jan. 24, 2011 Location: Inver Grove Heights, Minn. Inspection dates: Oct. 4-15, 2010	QS and pre-market reg violations identified at manufacturer of decorative, corrective and non-corrective rigid and soft contact lenses. The company failed to establish and maintain a quality system. The firm also was selling its lenses without pre-market approval or pre-market clearance from FDA. [Issued by Minneapolis District Office]
E.A. Beck & Co. Warning letter date: Dec. 14, 2010 Location: Costa Mesa, Calif. Inspection dates: Aug. 10-25, 2010	QS, MDR and pre-market reg violations identified at manufacturer of the ***Erich*** Arch Bar, ligature ties and other devices. The company failed to establish and maintain procedures for corrective and preventive action and complaint handling. Software used for generating labels was not validated. The heat-sealing process to seal product packing was not validated for dental pliers and other products. Device master records and device history records were not established and maintained. Labeling procedures also weren't established and maintained. MDR procedures were not created. Finally, the firm was selling the Erich device without pre-market approval or pre-market clearance from FDA. [Issued by Los Angeles District Office]
Marquette General Health System IRB (dba Precision Reproduction) Warning letter date: Jan. 18, 2011 Location: Marquette, Mich. Inspection dates: Oct. 18-21, 2010	Institutional review board cited for violation of IRB, IDE and human subject protection regs. The IRB's consent form lacked required information, and the IRB did not submit progress reports to IRB members. The IRB also voted on research during meetings without at least one member in attendance whose primary concerns were in nonscientific areas. IRB activities and meeting minutes were not documented. The IRB's response to the FDA-483 was deemed inadequate. [Issued by CDRH]
Napoli LLC IRB Warning letter date: Jan. 21, 2011 Location: Beverly Hills, Calif. Inspection dates: Aug. 24-Sept. 24, 2010	Institutional review board cited for violation of IRB regs. The IRB was composed of only two individuals; FDA requires a minimum of five. The IRB also didn't have procedures governing its functions and operations. [Issued by CDRH]
Orthocon Inc. Warning letter date: Jan. 6, 2011 Location: Irvington, N.Y. Inspection dates: July 13-Sept. 9, 2010	Sponsor of clinical study cited for IDE reg violations. The firm failed to secure investigator compliance; for example, the study investigator was implanting devices in subjects who met exclusion criteria. The firm's response to the FDA-483 was deemed inadequate. [Issued by CDRH]

Description	Summary
Syneron Inc. Warning letter date: Dec. 23, 2010 Location: Irvine, Calif. Inspection dates: Aug. 3-6, 2010	QS and pre-market reg violations identified at manufacturer of the ***eMax*** System. The company failed to establish and maintain procedures for acceptance activities and complaint handling. The firm also was selling the eMax device without pre-market approval or pre-market clearance from FDA. [Issued by Los Angeles District Office]
Tosoh Biosciences Inc. Warning letter date: Jan. 18, 2011 Location: Grove City, Ohio Inspection dates: March 23-May 27, 2010	Manufacturer of High Performance Liquid Chromatographs (HPLC), cited for QS, pre-market, and correction & removal reg violations. The firm failed to establish and maintain complaint handling procedures, and complaints were not investigated; for example, 10 CPU boards were replaced at customer sites, but the board failures were not considered complaints, nor were they investigated. Service reports were not adequately analyzed using appropriate statistical methodologies. Corrective and preventive action procedures were not established and maintained. Complaints were not reviewed and evaluated for MDR reportability. Production processes were not developed, conducted, controlled and monitored. Equipment calibration procedures weren't established and maintained. Device master records weren't maintained. Further, procedures for acceptance activities were not established and maintained. In addition, the firm sent four informational bulletins to customers to make changes to the product, but the company did not report those field corrections to FDA. Finally, the firm was selling the HPLC product without pre-market approval or pre-market clearance from FDA. The firm's response to the FDA-483 was deemed mostly adequate. [Issued by Cincinnati District Office]
Verichem Laboratories Inc. Warning letter date: Dec. 16, 2010 Location: Providence, R.I. Inspection dates: Sept. 14-Oct. 29, 2010	QS reg violations identified at manufacturer of clinical chemistry reference materials for in vitro diagnostic use. The company failed to conduct design validation on data analysis software used in products. Procedures to control nonconforming product were not established and maintained. The firm's response to the FDA-483 was deemed inadequate. [Issued by New England District Office]

NEWS IN BRIEF

2011 plans for warning letters, UDI program, eMDRs

CDRH is pledging to develop strategies by the end of May to improve the development and clearance of warning letters. The goal, which includes getting the letters in the mail faster, is to implement the new policies beginning this fall, according to the center's strategic priorities report, released Jan. 19. The report also notes that a proposed rule to require Unique Device Identifiers (UDIs) for all devices should be out by June 30. Originally the center aimed to have the UDI rule out by the end of 2010 ("The Silver Sheet" December 2010). Final requirements for mandatory electronic Medical Device Reporting (eMDR) also should be out by June 30. The purpose of the program is to enhance CDRH's ability to analyze adverse event reports and identify troubling patterns more efficiently ("The Silver Sheet" September 2009).

The 2011 goals are more modest than those outlined for 2010, CDRH acknowledges in the report. In 2010, the device center set out an ambitious agenda for pre-market review improvements, communication and transparency initiatives, and innovation efforts. The agenda last year "required staff to go above and beyond their already demanding day-to-day responsibilities," FDA said in the report. "While we should always stay vigilant for opportunities to improve, we cannot and should not sustain an environment of constant change and accelerated effort."

Dental products seized

U.S. marshals seized all dental devices made by Hialeah, Fla., firm Rite-Dent Manufacturing Corp. on Jan. 5 and 6. The seizure of $208,910 worth of products follows FDA inspections that found continuing significant quality system deficiencies in Rite-Dent's manufacturing processes. The company also failed to obtain FDA pre-market approval or clearance for its ***Ultra Impression*** system. The agency warned the company about these and other violations in three separate inspections and a 2005 warning letter ("The Silver Sheet" January 2006). The letter noted that the firm didn't conduct quality audits and failed to establish procedures for complaint handling, corrective and preventive actions, acceptance activities, and employee training, among other quality system violations.

Rare Sec. 522-related warning letter

FDA cited spinal implant and surgical instrument developer Alphatec Spine in a Jan. 11 warning letter for post-market surveillance study violations involving the firm's ***Zodiac DynaMo*** and ***Isobar*** semi-rigid spinal systems and Isobar semi-rigid dual dampener. (*See Warning Letters, p. 60.*) In October 2009, the agency used its authority under Sec. 522 of the Food, Drug and Cosmetic Act to order Alphatec to conduct post-market surveillance on all three products. Sec. 522 studies can be imposed on Class II and III devices that are life-sustaining or life-supporting; are implanted in the body for more than a year; have significant use in pediatric populations; or whose failure would likely lead to serious health consequences.

FDA alerted Alphatec last July that its Sec. 522 study protocol lacked information needed for FDA to complete its review. The agency later identified revisions or information the company needed to submit before its post-market surveillance plan could be approved. According to the warning letter, the three devices are misbranded because Alphatec failed to revise the post-market surveillance plan and address FDA's concerns within the specified timeframe. Sec. 522 post-market studies are less common than traditional post-approval studies, which FDA can require as a condition of approval for any high-risk Class III device. However, the agency has said it is considering making greater use of Sec. 522 studies, where appropriate, because they carry heavy enforcement weight.

User fees for post-market surveillance?

Medical and consumer groups say future user fees should be used for additional post-market surveillance, not just toward speeding up product approvals. FDA is seeking input from medical professional societies, as well as consumer and patient-advocacy groups, on device industry user-fee reauthorization. Current user-fee levels are set through September 2012, at which point new legislation must be passed to reauthorize the industry-paid fees and determine how they should be used.

FDA first met with medical, patient and consumer groups Jan. 13, and plans to hold monthly meetings to continue receiving input. "One of the big messages was 'safety rather than speed,'" said Diana Zuckerman, president of the National Research Center for Women and Families, who attended the Jan. 13 closed-door meeting. "We understand speed is good, but the resources FDA needs to ensure safety are more important." Other meeting attendees included the Consumers Union, WomenHeart and two orthopedic surgeon societies, Zuckerman said.

More 'town hall' meetings

CDRH Director Jeffrey Shuren will kick off a new round of "town hall" discussions with industry and other interested stakeholders March 10 in Irving, Texas, near Dallas. He and other device center officials will discuss CDRH's strategic priorities for 2011 and other topics of interest to attendees. Shuren conducted three town hall meetings last year.

CDRH ombudsman report released

CDRH's ombudsman fielded 414 complaints, disputes and other inquiries last year – up 65 percent from 2009, when it received 250 – according to the center's 2010 ombudsman report. Most inquiries and complaints came from industry, and the most common subject of the inquiries was CDRH policies and procedures (46.6 percent), followed by questions about data and testing requirements (10.4 percent). As of Jan. 1, 2011, 352 of the cases were closed.

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