# Food and Drug Administration

Center for Devices and Radiological Health

# Global Unique Device Identification Database (GUDID)

## User Manual

Version 1.0

Date: April 24, 2014

# Table of Contents

# 1 Introduction

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, the nation's food supply, cosmetics, dietary supplements, and products that give off radiation; and for regulating tobacco products.

Section 226 of the FDA Amendments Act (FDAAA) of 2007 and Section 614 of the FDA Safety and Innovation Act (FDASIA) of 2012 amended the Federal Food, Drug, and Cosmetic Act to add section 519(f), which directs FDA to promulgate regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The Unique Device Identifier (UDI) Proposed Rule was published on July 10, 2012, followed by an amendment, published on November 19, 2012, modifying the implementation time frame for certain devices. In developing the proposed rule, FDA solicited input from a variety of stakeholders (e.g., manufacturers, global regulatory bodies, the clinical community, patient advocates) to ensure that as many perspectives were incorporated as possible. The UDI Final Rule was published on September 2013. Over the past year, FDA has been working on the design and development of the Global Unique Device Identification Database (GUDID).

This document is intended primarily to provide information about submitting data to the database for device Labelers[1], entities that will be responsible for providing the data to the GUDID. Please note that database enhancements will continue, to improve user experience, build in better validation rules, and make other necessary changes as we "learn" from the initial roll-out and implementation. The FDA intends to periodically update this document to reflect system changes and enhancements.

FDA's Guidance documents, other Technical documents and FAQs, including this technical document, do not establish legally enforceable responsibilities.

[1] The UDI Final Rule (http://www.fda.gov/udi ) defines labeler as "any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and, any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler."

## 2 How to obtain a GUDID Account

In order to submit data to GUDID, first an Organization account needs to be established. In order to do so, please refer to Global Unique Device Identification Database (GUDID) - Draft Guidance for Industry (PDF - 3.6 MB) . Visit www.fda.gov/udi to obtain an organization account.

## 3 Getting Started

### *3.1 Browser Compatibility*

**GUDID currently supports the following browsers:**

- Internet Explorer 9 and 10
- Mozilla FireFox 17-22

**Troubleshooting Internet Explorer Issues**

If you are using Internet Explorer (IE) 9 or 10 and see the following message, Follow the instructions below to troubleshoot.


Text: Warning! Your web browser is not supported for this GUDID release. Please use a supported browser which is available under the About link. Sorry for any inconvenience.

**Turn off Compatibility View in Internet Explorer 9 and 10**

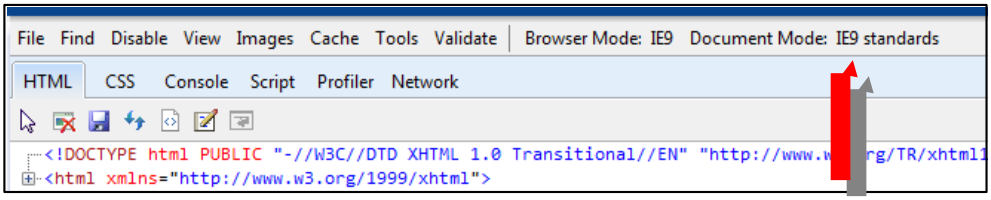
1. Open GUDID in Internet Explorer.
2. See if the Compatibility View button appears in the Address bar. (If you don't see the button, there's no need to turn off Compatibility View.)


3. Tap or click the Compatibility View button to turn off Compatibility View.

4. The Compatibility View button should now appear grayed out:


**Change Mode and Document version**

1. Open GUDID in Internet Explorer.
2. Click F12 on the keyboard, or click the  con in the right hand corner and click on Developer Tools.
3. In the top toolbar set the Browser Mode to IE9/IE10 and the Document Mode to IE9 standards/IE10 standards.

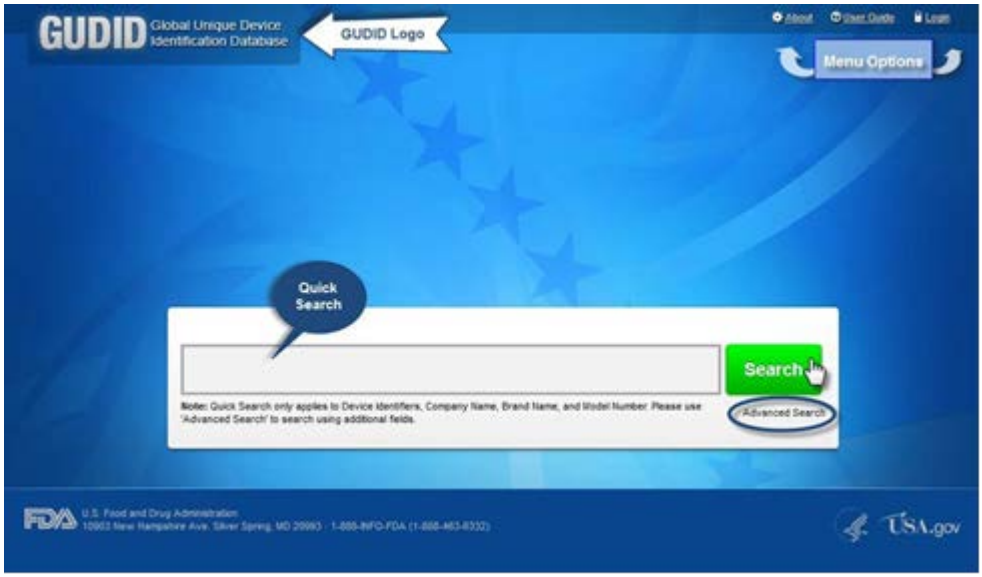



### *3.2. Common Functions*

**Main Page**

URL: https://gudid.fda.gov/gudid

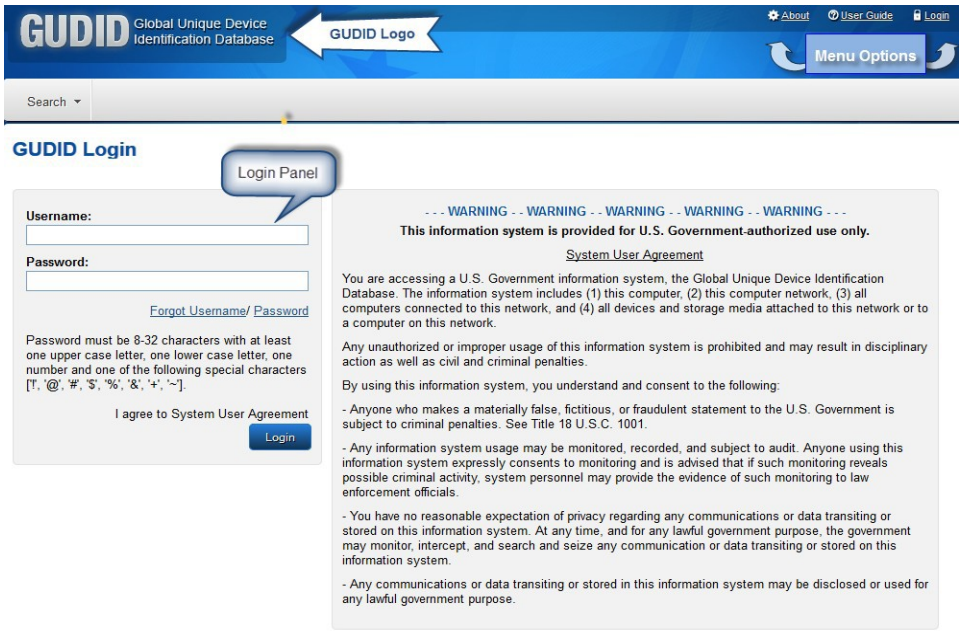
The *Main Page* is displayed as shown below. From this page you can login, search, among other functions as described in this document.



## Login Screen

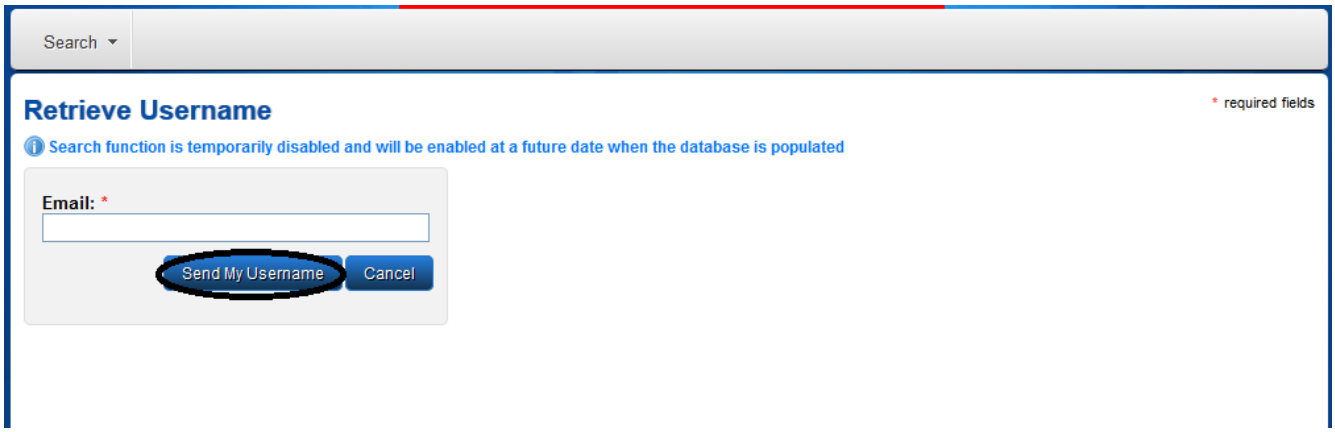
From the GUDID log in screen, enter your username and password for account management or data entry. Please review the System User Agreement prior to logging into the GUDID. At the first login, you must change your password.

> ***Note to system users: When the Search functionality is enabled; the search capabilities will be available as a front-end Public Portal to the GUDID. No login information will be required. This public search will be restricted to non-proprietary data.***

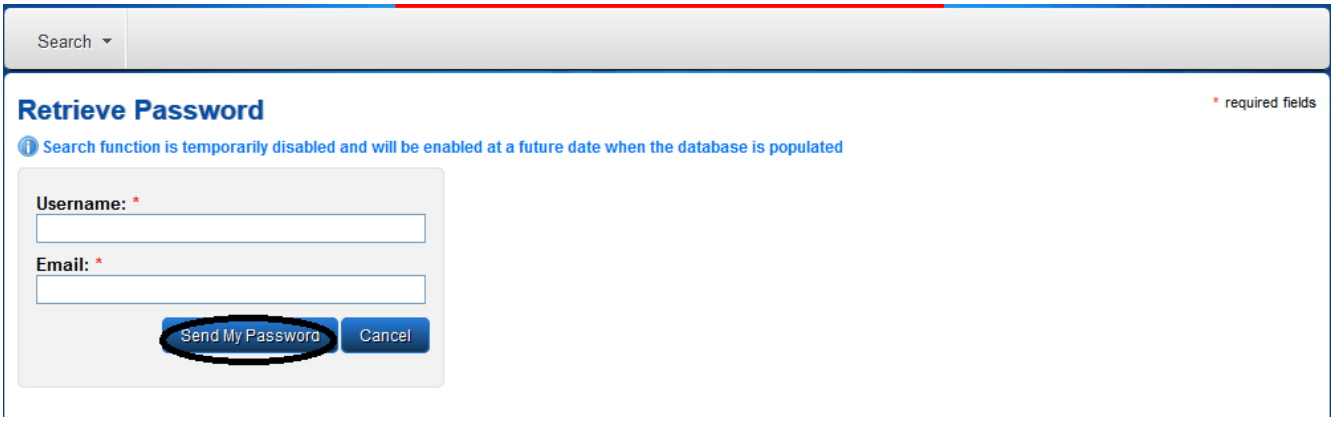



## Username and Password

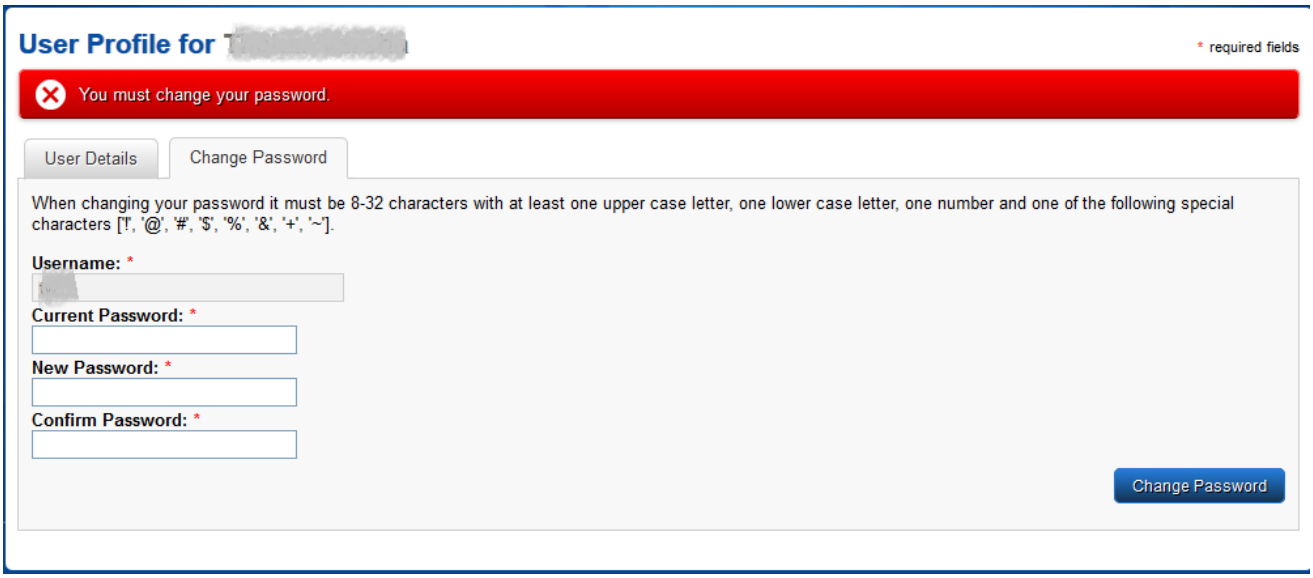
To retrieve a forgotten username, click **Forgot Username.** Enter email address associated with the username, and then click **Send MyUsername.** You will receive an email with the username. If you have more than one account linked to your email, you will receive an email for each username in GUDID. Note: This function does not reset the password.


If you forget your password, click **Password.** Enter username and email associated with the password. Click **Send My Password.**




You will receive two emails: 1) Password reset notification; 2) Temporary password. Login to the GUDID with the temporary password and your username. The system will then ask you to change your password.

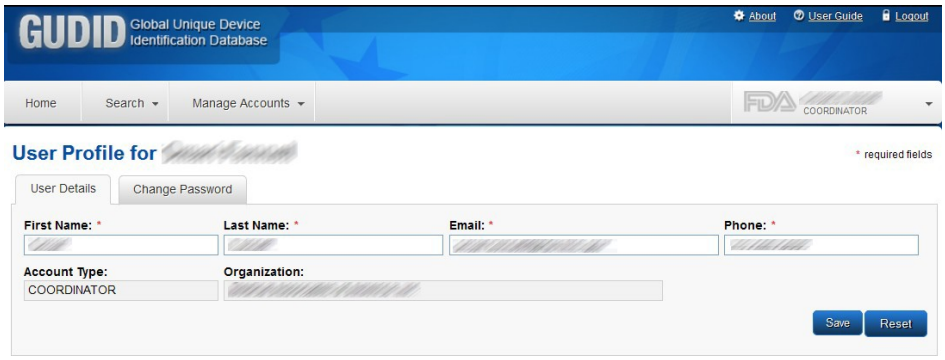



*You must change your temporary password to access GUDID functions. Enter the temporary password, a new password, and confirm your new password.*

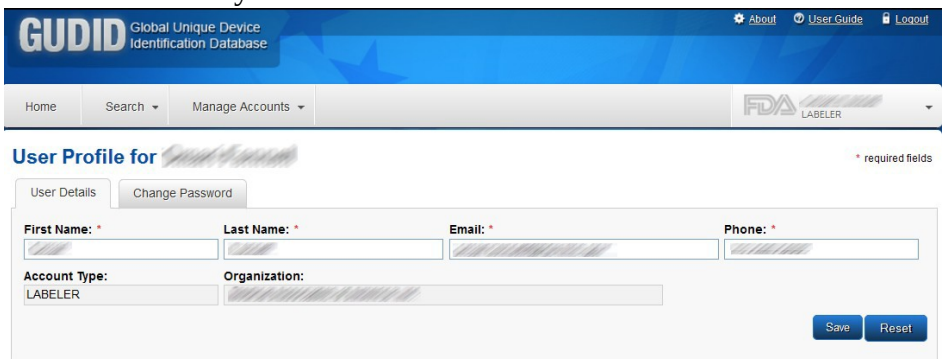
**View and Edit User Profile** To view the **User Profile**, click on the dropdown menu next to the username and role in the right hand corner. On the **User Profile** screen, you can make updates

and save changes by clicking **Save** on the *User Detail* tab, or Change your password on the *Change Password* tab.

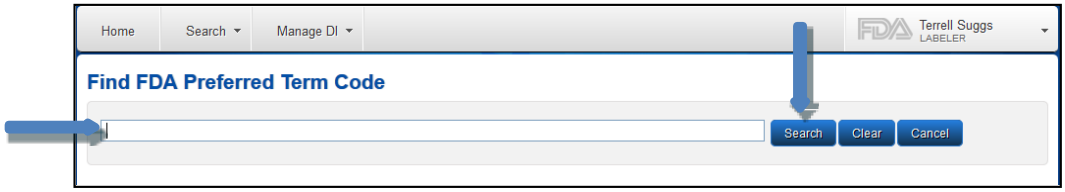
Coordinator:




Labeler Data Entry User




**FDA PT Code**

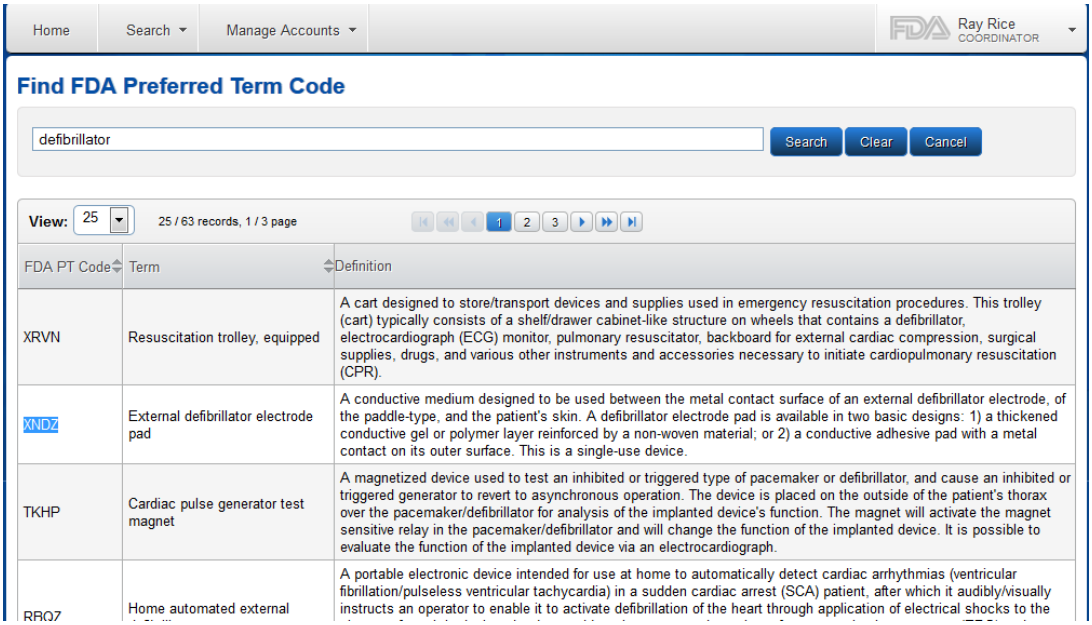



The **Find FDA Preferred Term Code** functionality is available to all logged in users and will allow a search on the Global Medical Device Nomenclature (GMDN)[2] Preferred Term Name or GMDN Definition, to retrieve the FDA Preferred Term (PT) Code.

[2] Global Medical Device Nomenclature (GMDN) is a system of internationally agreed descriptors used to identify medical device products and is managed by GMDN Agency. Visit: http://www.gmdnagency.com/default.aspx

After entering GMDN Preferred Term Name or Definition text, and clicking the **search button**, the search results will display a list of active **FDA PT Code**, associated GMDN **Term**, and GMDN **Definition** from the database related to the keywords provided in the **search text field**.

For example, a search for the GMDN Term '*defibrillator*' will yield the results as shown:




Highlighted in the picture above is the **FDA PT Code** for the GMDN Preferred Term Name "External defibrillator.electrode.pad".

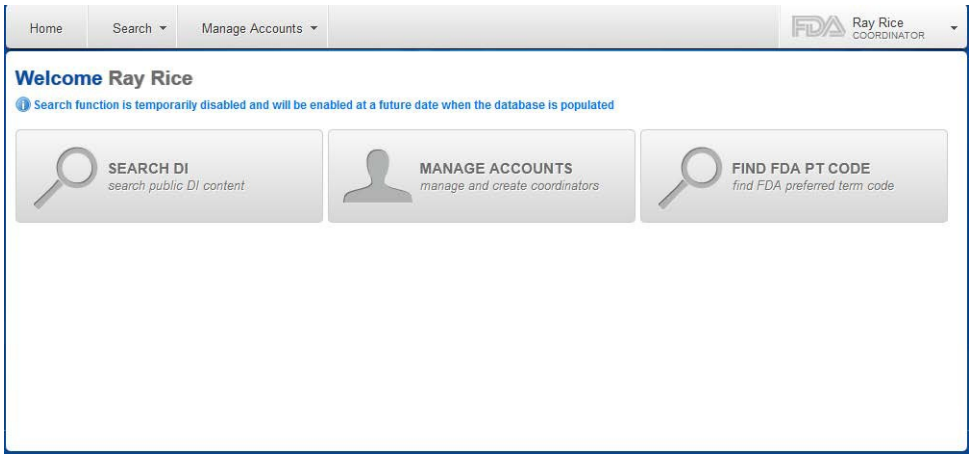
The results will show the **FDA PT Code**, the **Term** (GMDN Preferred Term Name), and the **Definition** (GMDN Definition) providing details of the active GMDN code.

***Note to system users: The GMDN is not a codeset owned by FDA. For any questions regarding GMDN Codes or how to access a full list of these terms, please contact the GMDN Agency at https://www.gmdnagency.com/***

### *3.3 Coordinator*

## Overview of Functions available for a Coordinator Role

## Coordinator Home Page




## Search DI

**Search DI** allows a Coordinator to search for public DI records.

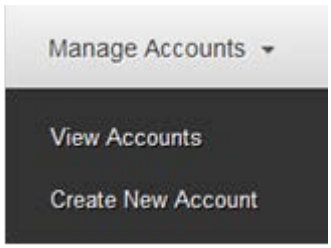
*Note: This functionality is temporarily disabled and will be enabled when Public Search is made available.*

## Find FDA PT Code


**FDA PT Code** allows a Coordinator to search for a GMDN Preferred Term or GMDN Definition, and retrieve the FDA assigned Preferred Term Code (See FDA PT Code) (The FDA PT Code is mapped to the GMDN code)

## Manage Accounts


**Manage Accounts** allows a Coordinator to view and manage Labeler Data for their assigned Labeler DUNS Number.




The drop-down menu of **Manage Accounts** allows a Coordinator to navigate to **View Accounts** or **Create New Account**

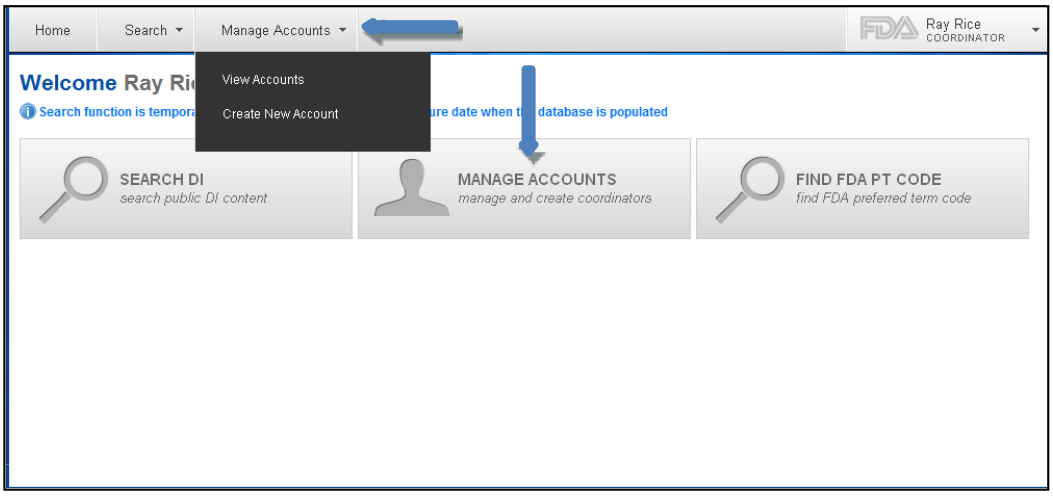
### Access the Database

To begin, Login into GUDID as a Coordinator (see Subsection 2.2 for detailed information).

The home is displayed at login, see figure below.

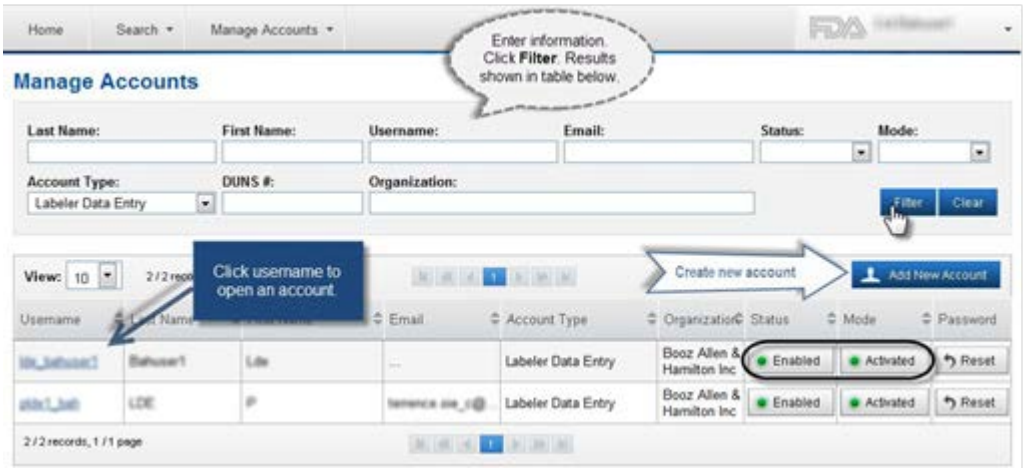
Click the **Manage Accounts** button or select the **Manage Accounts** from the menu bar.

Note: A username and temporary password will be sent to the LDE user when the Coordinator creates an account.

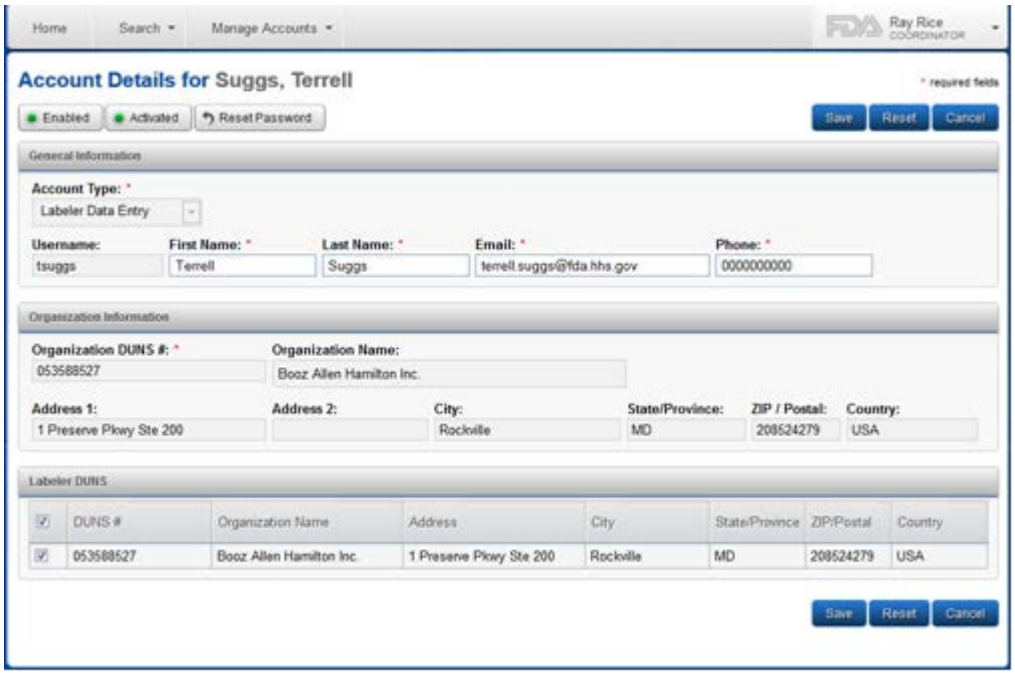


## Manage Accounts

Upon entry, **Manage Accounts** will display all accounts available for you in a table. You can filter for a specific account by typing in any of the fields provided – Last Name, First Name, User Name, Email, Status, Mode, etc. Enter information into the field you desire to filter by, and then click **Filter.** The results of the filter appear in the table at the bottom of the page.




Click on the *username* link to see account details.




You can edit the account details, and then click **Save.**

**Account Status and Mode**

An account can have an enabled or disabled status. An enabled account is able to login in to GUDID. A disabled account cannot login to GUDID and must have the account re-enabled by a coordinator. Re-enabling the account automatically changes the user's password to a temporary password notifies the user of the change via an automated email. The temporary password must be changed before GUDID access is restored.

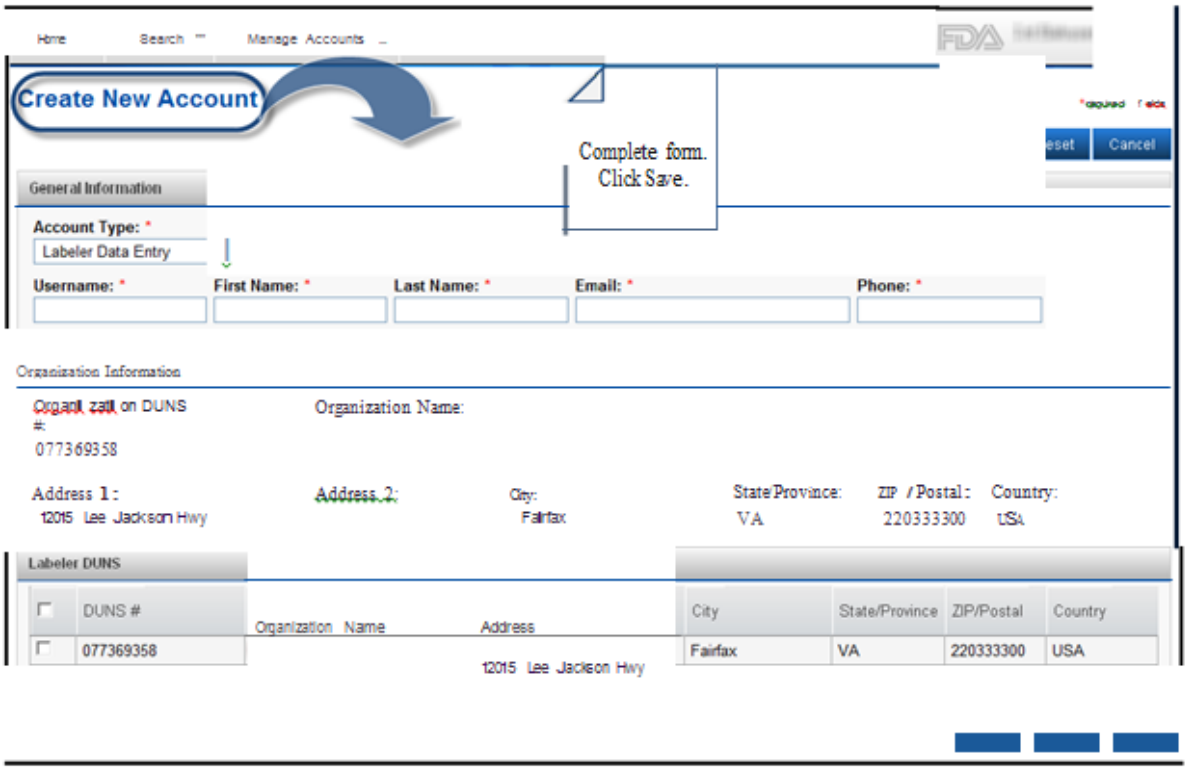
An account can also be inactivated or deactivated mode. The default for each account is activated mode. If an account is set to deactivated, then the account cannot access GUDID and that account cannot be recovered.

On the Manage Accounts and Account Details screen you can change the status and mode by clicking **Enabled/Disabled** and **Activated.** You can also reset the user's password which will cause the user

to receive a temporary password via email.

**Create New Account**

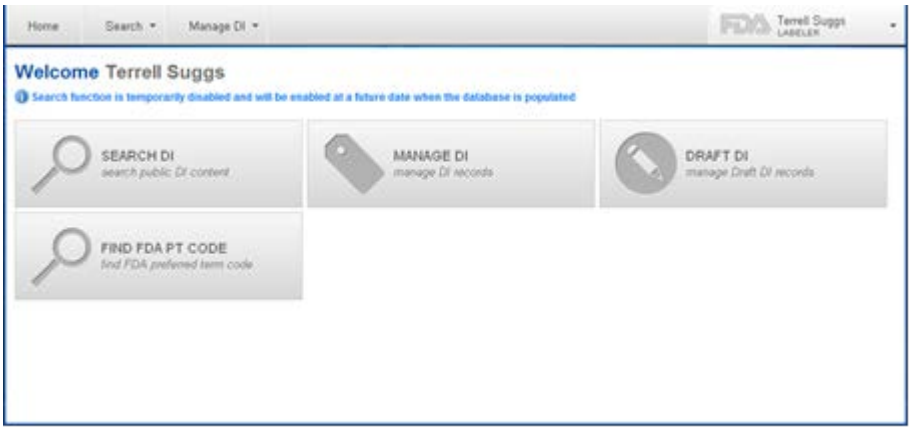
To create a new account, click Add New Account on the Manage Accounts page. On the Create New Account page, enter the required information to create a new account. When complete, click Save.




### *3.4 Labeler Data Entry (LDE) User*

**Overview of Functionality for Labeler Data Entry (LDE) User Role**

**Labeler Data Entry User Homepage**




**Search DI Records**

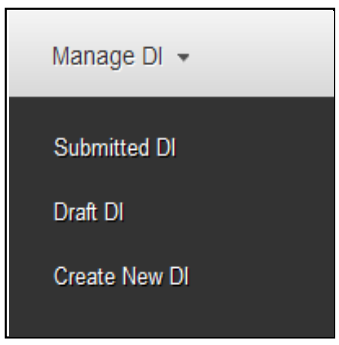

**Search DI** allows a LDE user to search for public DI records.

*Note: This link is temporarily disabled and will be enabled when Public Search is made available.*

**Find FDA PT Code**


**Find FDA PT Code** allows an LDE to search for a GMDN Preferred Term of GMDN Definition, and retrieve the FDA-assigned Preferred Term Code.

**Manage DI Records (drop-down)**



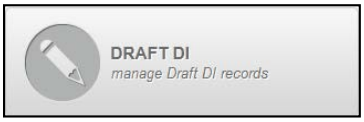
**Manage DI** allows an LDE User to create and manage DI records for their assigned Labeler DUNS numbers.

The **Manage DI** drop down allows an LDE User to navigate to **Submitted DI, Draft DI or Create NewDI** functionality.

### Manage DI Records


The **Manage DI** icon will navigate the user to their Submitted DI records. This includes Published and Unpublished DI Records.

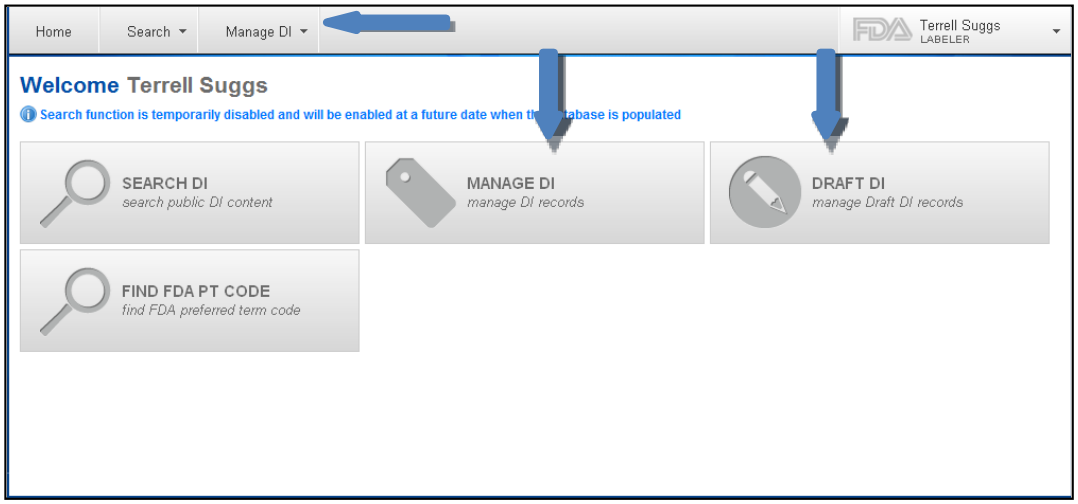
### Draft DI Records




The **Draft DI** icon will navigate the user to their Draft DI records. The Draft DI records can only be viewed by the user that created the record. See examples in Appendix F.

**Access the Database**

To begin, login as LDE user (see Login section under Subsection 2.2 for detailed information). The home page is displayed at login, see figure below. Click the **Manage DI** and **Draft DI** buttons or **Manage DI** from the menu bar.




**Manage Device Identifier (DI) Records**

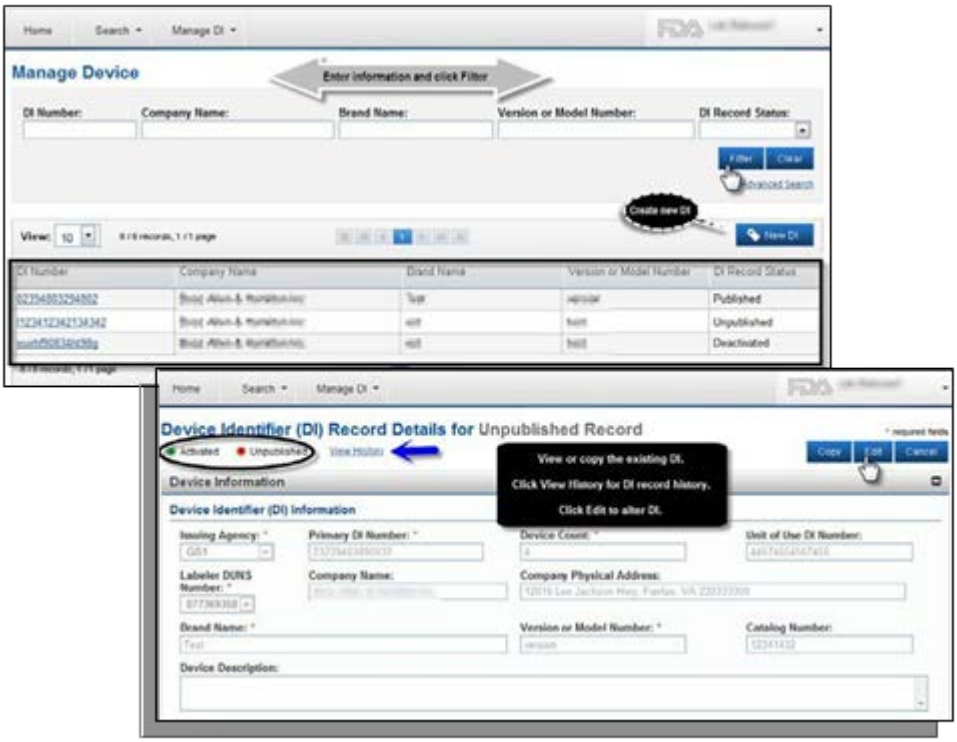
Upon entry, on the **Manage Device** page, published and unpublished DI records available for view will be displayed in the table. Click on a DI number to see DI record details.

You can filter for a specific DI record by typing in any of the fields provided – DI Number, Company Name, Brand Name, Version or model number, or DI Record Status (Published/Unpublished). Enter information into the field you desire to filter by and click **Filter**. Results will appear in table at bottom of screen. Click DI Number link to open DI record.

Open a published DI record from the **Manage Device** list. You will see on the top left to Device Identifier Details page that the DI record is Published.

Open an unpublished DI record from the **Manage Device** list. You will see on the top left of the Device Identifier Details page that the DI record is Unpublished.

> ***Note to system users: The device manufacturer cannot change a DI record status from Published to Unpublished without intervention from FDA staff.***



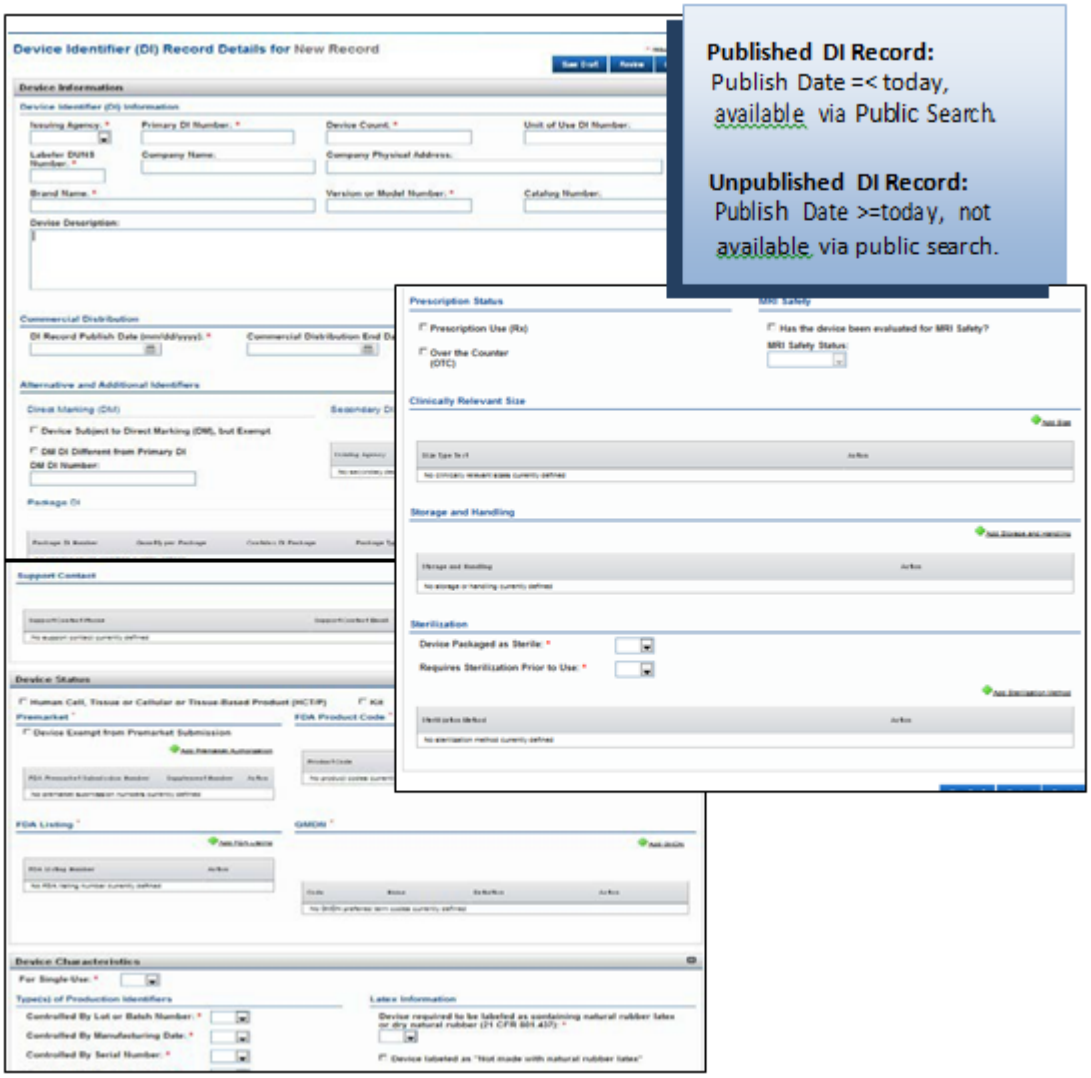
**Create New DI Record**

When you click the New DI button, the DI Record Details screen will open up. Complete the **DI Record Details** for a new DI record. Click **Save Draft** if you have not completed the form (you must include at least the Primary Issuing Agency and Primary DI Number to save as draft). Draft DI records will appear on the Drafts DI screen for future editing (system will purge Draft DI records after 180 days from the last modified date).

Please refer to Sample DI Record for examples data entry use cases.

To submit a DI record, you must provide a valid GMDN code or an FDA Preferred Term Code (PT) Code. For assistance in understanding the GMDN description and with GMDN code assignment, we refer you to GMDN Agency. To look up a valid FDA PT Code, use the **Find FDA PT Code** feature as shown in FDA PT Code.

Click **Review** after you have completed the DI record. The system runs business rules on entered information to ensure all entries are valid and all required fields have values. If the DI record has errors, the user must correct the errors and click review again. Once the record is validated, the system notifies the user that the Review was successful. When the user clicks **Submit,** the DI record will be in Published or Unpublished state based on the DI Record Publish Date.

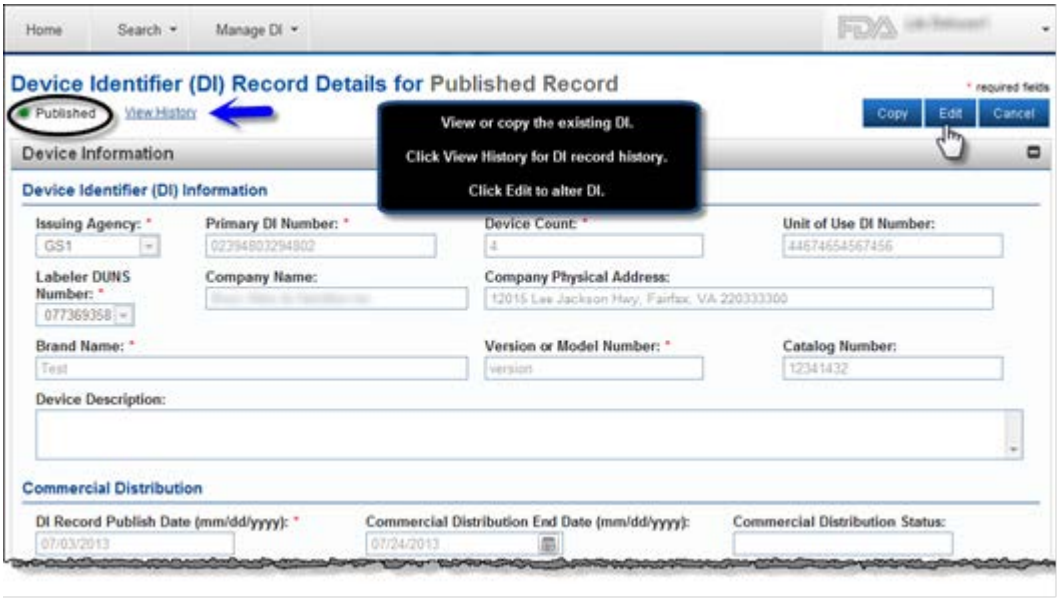



If the DI record is Published, the labeler will have 7 Calendar days called ‘Grace Period’ to edit any fields on the DI record. After the grace period expires, non-DI trigger fields are editable on the Published DI record. The grace period will not start for an Unpublished DI record until the DI record is Published.

**Edit Existing DI Record**

Open a published DI record from the list. You will see on the top left of the screen that the DI record is **Published**. Click **Edit** at top or bottom right the page. Update the information as you desire. After editing, click Review and Submit to save changes.

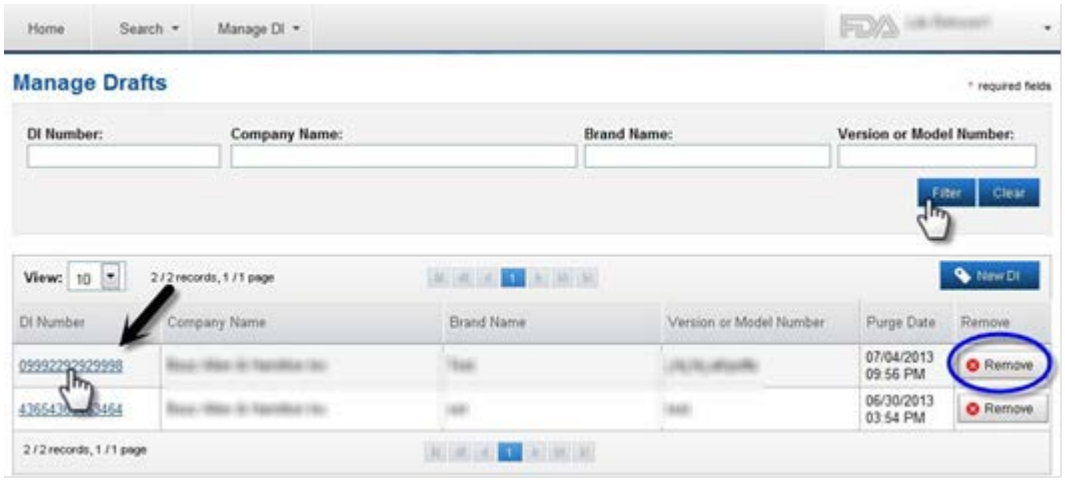
Open an unpublished DI record from the list. You will see on the top left of screen that the DI record is **Unpublished.** Click **Edit** at the top or bottom of the page. Change the form as needed. After editing, click Review and Submit to save changes. Note that the Unpublished DI allows you to edit all the fields without limitation.



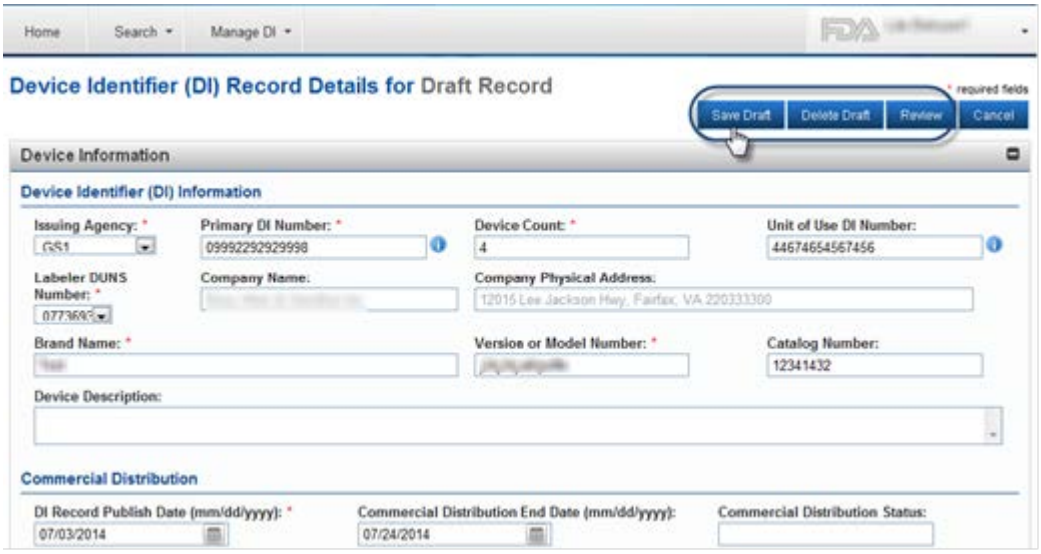

**Manage and Edit Draft DI Record**

To manage draft DI records, click the **Draft DI** record button or **Draft DI** record link under the **Manage DI** dropdown. You will be returned with all of the Draft DI Records. You can choose to remove a Draft DI record permanent by clicking the **Remove** button.

To narrow the list of results, you can filter by DI number, Company Name, Brand Name, and Version or Model Number. The results of the filter appear in the table at the bottom of the page




Click a DI number to open the DI Record Detail. You can **Edit, Save Draft, Delete Draft, Review or Cancel.** The **Save Draft** button will save the draft as long as the DI record contains a primary issuing agency and primary DI number. The **Delete Draft** button will permanently remove the draft. The **Review** button will perform validation on the DI record and if it passes, the record can be submitted. The **Cancel** button will change all changes and return the DI record back to its last saved version.



## Copy Existing DI Record

Only Published and Unpublished DI records can be copied. To copy a DI record, go to the Manage DI page and click on the DI number you would like to copy. Click Copy to create a copy of the DI record. The copied data displays on the DI Record Details for New Record form.


***Note to system users: When working with a copied DI record (whether published or unpublished) please ensure to change all data fields to accurately capture the device information in the database.***

### *4.1 Package DI Label*

("Not all fields in GUDID are required to be on the label. This example is for illustrative purpose only")

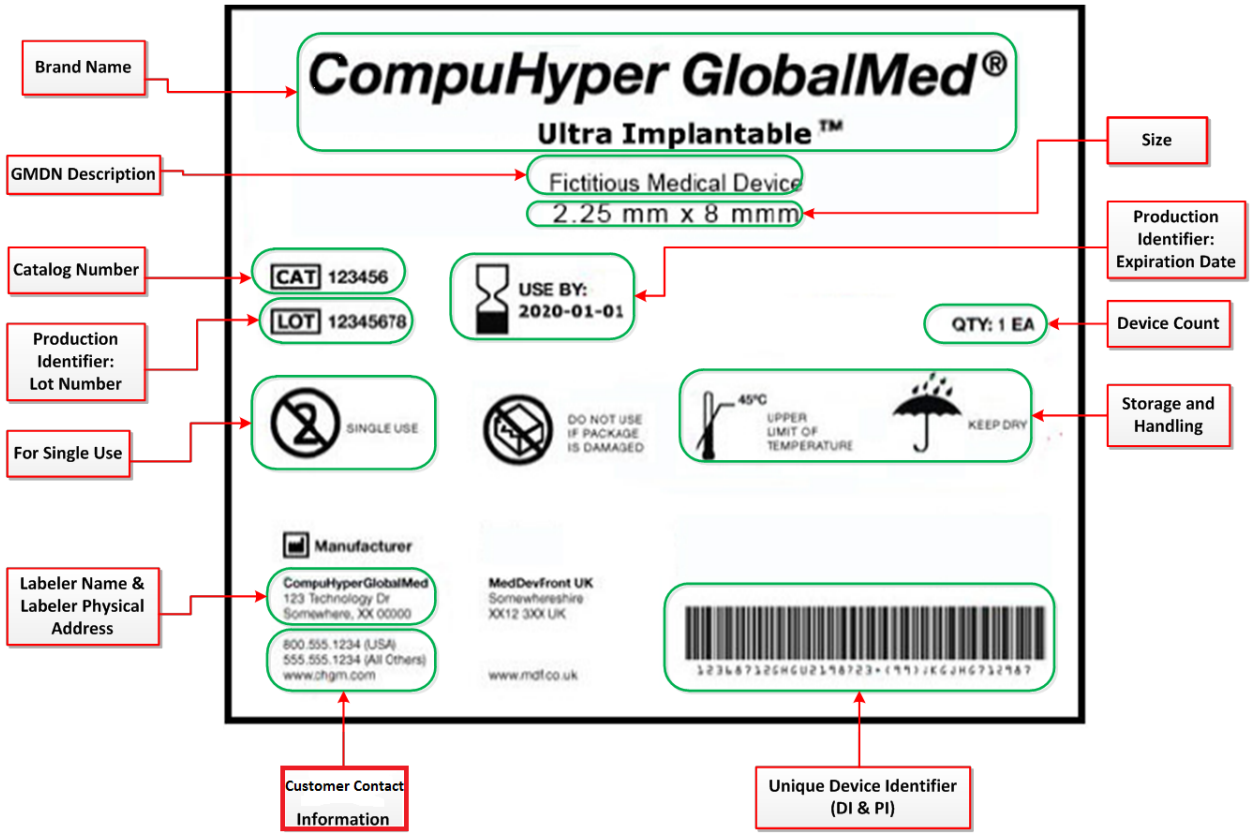



**Figure 1: Fictitious Medical Device label**

### *4.2 GUDID Sample Record of an Unpublished Record*

#### 4.2.1 Creating a New DI Record

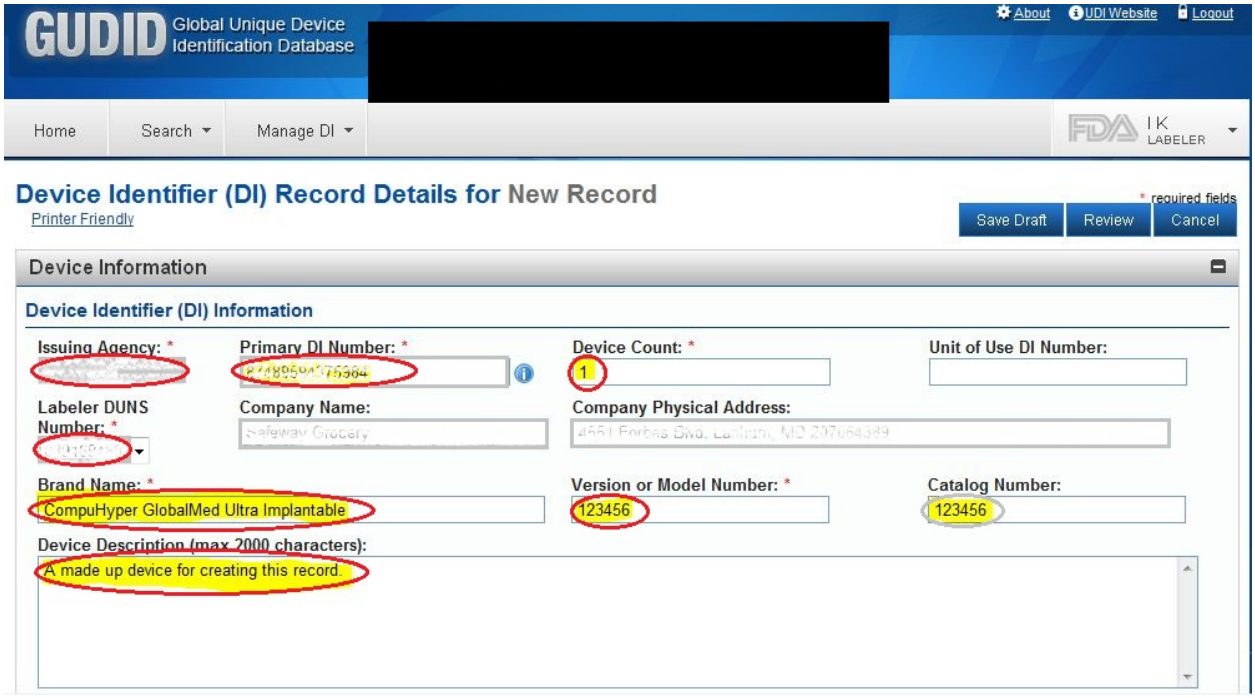



**Figure 2 Screenshot of GUDID interface**

The fictitious medical device label in Figure 1 is used as an example to create this new DI record in GUDID. To enter Device Identifier (DI) information related to your medical device.

-Select your Issuing Agency from the drop down list. This is a required data element hence; an Issuing Agency must be selected.
-Enter Primary DI Number & Device Count. These are required data elements hence, entries must be made.
-Enter Unit of Use DI Number if applicable to your record.
-Select the appropriate Labeler DUNS Number from the drop down list. This is a required data element hence a Labeler DUNS Number must be selected.

-The Company Name and Company Physical Address is system populated through D & B Database.
-Enter Brand Name and Version or Model Number. These are required fields hence, entries must be made.
-Enter Catalog Number and Device Description.

Note that not all fields in GUDID are required. Fields that are marked with * are required data fields for GUDID. Rest of the information is required if it is available on the medical device label.

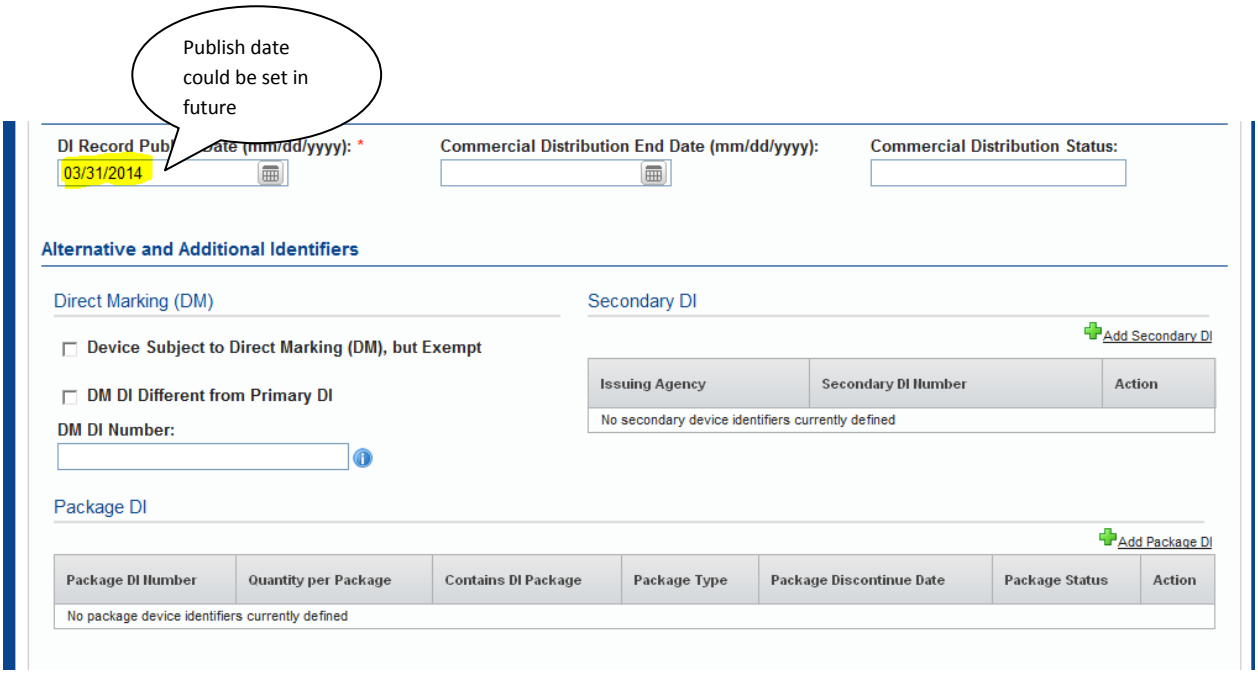



**Figure 3 Screenshot of GUDID Interface**

As you scroll down in the New Record window you will be able to enter Commercial distribution information of the device.

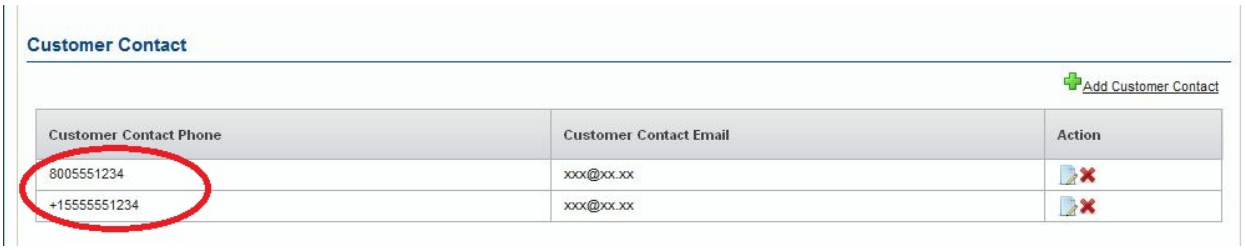
-Select or enter DI Record Publish date in mm/dd/yyyy format. This is a required data element hence; DI Publish Record Date must be selected.
-Select or enter Commercial Distribution End Date in mm/dd/yyyy format.
-Commercial distribution status field is system populated based on your entries in DI Record Publish date and Commercial Distribution End Date.

In the Alternative and Additional Identifiers section enter the following Direct Marking (DM) information if it applicable to your medical device for which the record is being created.

-Check the “Device Subject to Direct Marking (DM), but Exempt”
-Check “DM DI Different from Primary DI”. If the “DM DI Different from Primary DI” is checked then enter the DM DI Number.

For entering Secondary DI number
-Click on the Add Secondary DI
-Select the Issuing Agency from the drop down list
-Enter Secondary DI Number
-Action allows user to make changes to Secondary DI.

For entering multiple levels of packaging
-Click on Add Package DI
-Enter Package DI Number
-Enter Quantity per Package
-Enter Contains DI Package
-Enter Package Type
-Enter Package Discontinue Date (if applicable)
-Enter Package Status
-Action button allow users to edit the information




For entering Customer Contact information click on Add Customer Contact
-Enter Customer Contact Phone. If there is no phone number please enter 999-999-999
-Enter Customer Contact Email. If there is no email please enter xxx@xx.xx
- Action allows user to make changes to Customer contact.

When checkboxes are not checked value is set to “No”

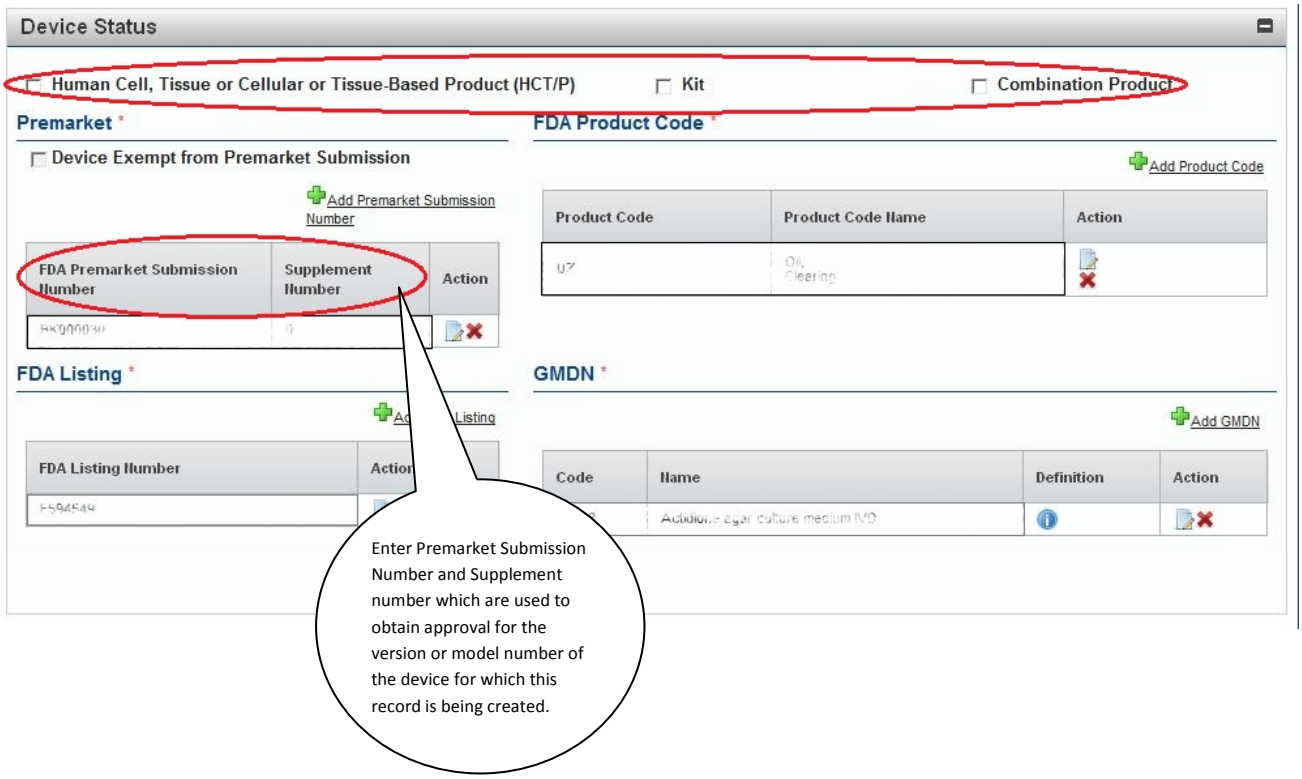



**Figure 4 Screenshot of GUDID interface**

In Device Status section
-Check if the device is Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)
-Check if the device is a Kit
-Check if the device is a Combination Product

For entering Premarket information
-Click on Add Premarket Submission Number
-Check if the device is exempt from Premarket Submission
-Enter FDA Premarket Submission Number and the Supplement Number
- Action button allow users edit the information

For entering FDA Product Code
-Click on Add Product Code
-Enter FDA Product Code
-Product Code Name is system populated from the FDA Premarket Submission database.

-Action button allow users to edit the information

For entering FDA Listing Number
-Click on Add Listing Number
-Enter a valid and relevant FDA Listing Number
-Action button allow users to edit the information

For entering GMDN Code
-Click on Add GMDN Code
-Enter GMDN Code
-Name will be automatically updated by the system
-Action button allow users to edit the information

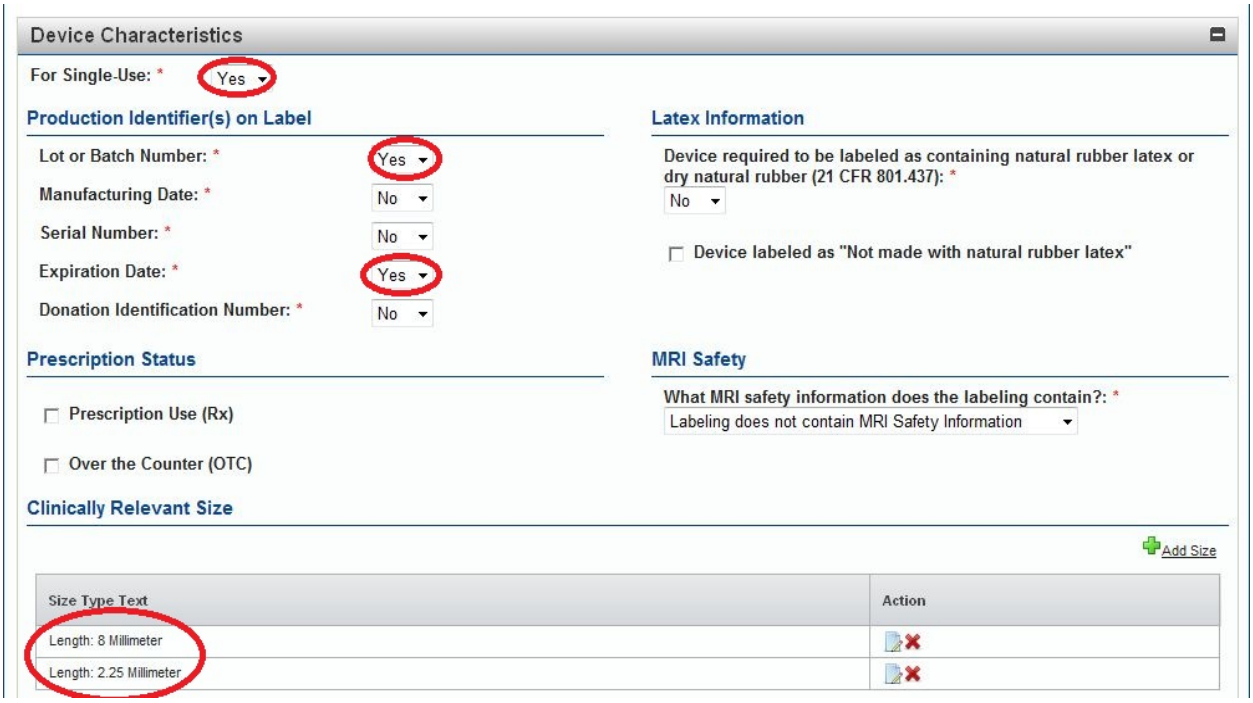



**Figure 5 Screenshot of GUDID interface**

In Device Characteristics section
-Select the appropriate value from the drop down list for whether the device is intended for single use. This is a required field and hence, a value must be selected.
-Enter the Production Identifiers on the Label and make appropriate selections from the drop down list for Lot or Batch number, Manufacturing Date, Serial Number, Expiration Date and Donation Identification Number. All these fields are required and hence, a value must be selected.

-Select a value from the drop down list for Device required to be labeled as containing natural rubber latex or dry natural rubber (21CFR 801.437). This is a required field and hence, a value must be selected.
-Check if the Device is labeled as “Not made with natural rubber latex”
-Check if the device requires Prescription Use (Rx)
-Check if the device is available Over the Counter
-Select a value from the drop down list as an answer for the question “What MRI safety information does the labeling contain? This is a required field and hence, a value must be selected.
-For adding clinically relevant
-Click on the Add size button.
-Action button allow users edit the information

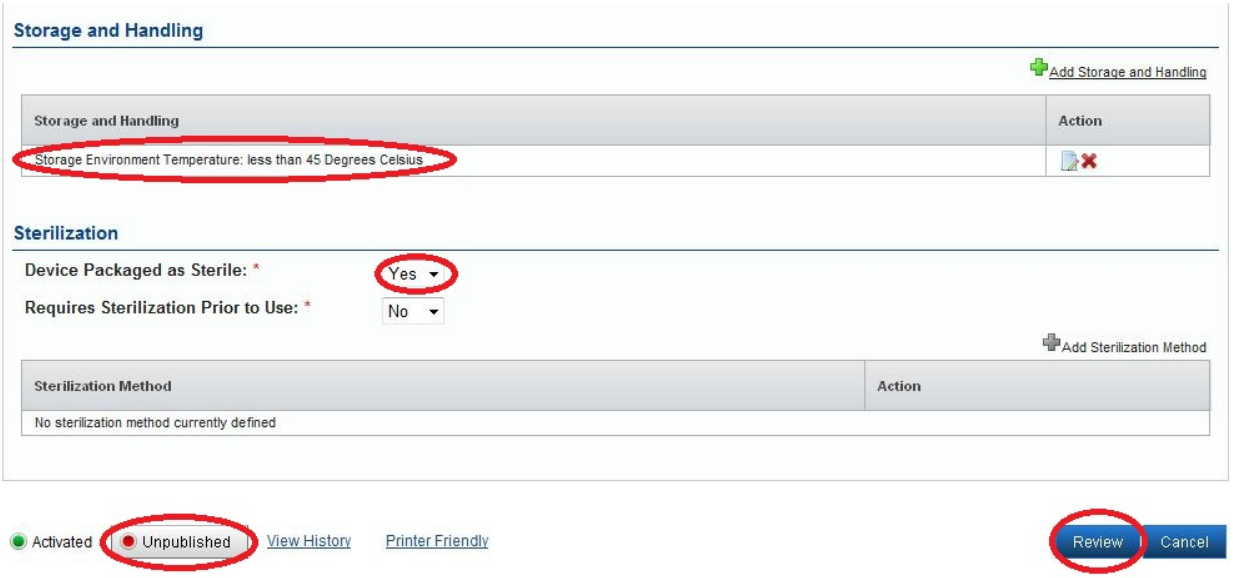



**Figure 6 Screenshot of GUDID interface**

For entering Storage and Handling information
-Click on the Add Storage and Handling button
- Action button allow users edit the information

Enter information related to Sterilization
-Enter/Select the appropriate entry from the drop down list for Device Packaged as Sterile. This is a required element hence, a value must be selected.

-Enter/Select the appropriate entry from the drop down list for Requires Sterilization Prior to Use. This is a required element hence, a value must be selected.
-Enter a sterilization Method by clicking on the Add Sterilization Method.
-Action button allow users to edit the information

Currently, the DI record is in an unpublished state
-Review checks whether the record has met all the system and business rules
-Cancel allows users to exit the screen without saving the record.

***Note to system users: Unpublished records can be edited unlimited number of times. However, after each edit records need to meet all the business rules as defined in the system. The system will automatically check for the publish date and move the records to published DI state on the day when publish date = today.***