



Food and Drug Administration



Center for Devices and Radiological Health

**Global Unique Device Identification Database (GUDID)
User Manual**

Version 1.0

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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 Labelers¹, 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.

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

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.)

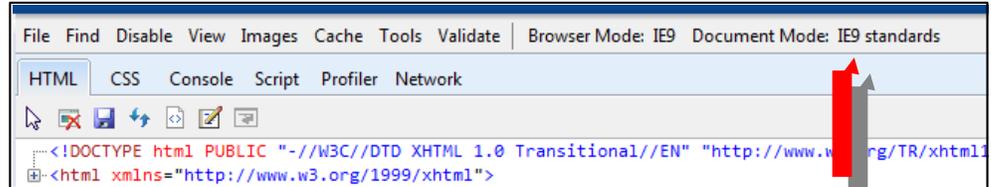


3. Tap or click the Compatibility View button to turn off Compatibility View.
4. The Compatibility View button should now appear grayed out:



Change Mode and Document version

1. Open GUDID in Internet Explorer.
2. Click F12 on the keyboard, or click the  icon 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.

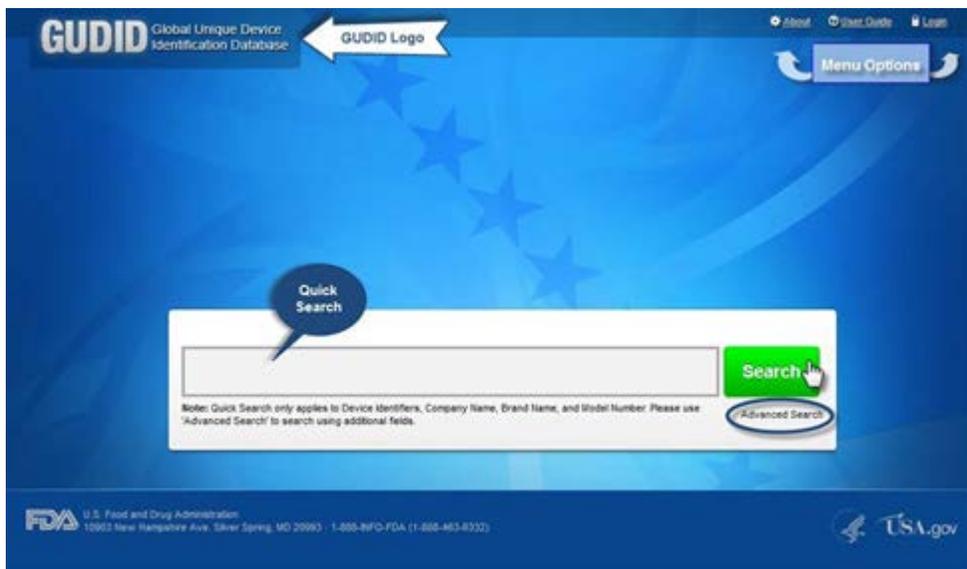


3.2. Common Functions

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.

GUDID Global Unique Device Identification Database

About User Guide Login

GUDID Logo Menu Options

Search

GUDID Login

Login Panel

Username:

Password:

[Forgot Username/ Password](#)

Password must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters [!, @, #, \$, %, &, +, ~].

I agree to System User Agreement

Login

--- WARNING --- WARNING --- WARNING --- WARNING --- WARNING ---

This information system is provided for U.S. Government-authorized use only.

[System User Agreement](#)

You are accessing a U.S. Government information system, the Global Unique Device Identification Database. The information system includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network.

Any unauthorized or improper usage of this information system is prohibited and may result in disciplinary action as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

- Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. See Title 18 U.S.C. 1001.
- Any information system usage may be monitored, recorded, and subject to audit. Anyone using this information system expressly consents to monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.
- You have no reasonable expectation of privacy regarding any communications or data transiting or stored on this information system. At any time, and for any lawful government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
- Any communications or data transiting or stored in this information system may be disclosed or used for any lawful government purpose.

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.

GUDID Login

 Search function is temporarily disabled and will be enabled at a future date when the database is populated

Username:

Password:

[Forgot Username](#) [Password](#)

Password must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters [!, @, #, \$, %, &, +, ~].

I agree to System User Agreement

--- WARNING -- WARNING -- WARNING -- WARNING -- WARNING ---

This information system is provided for U.S. Government-authorized use only.

System User Agreement

You are accessing a U.S. Government information system, the Global Unique Device Identification Database. The information system includes (1) this computer, (2) this computer network, (3) all computers connected to this network, and (4) all devices and storage media attached to this network or to a computer on this network.

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By using this information system, you understand and consent to the following:

- Anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties. See Title 18 U.S.C. 1001.

- Any information system usage may be monitored, recorded, and subject to audit. Anyone using this information system understands that monitoring and is advised that if such monitoring occurs

Search ▾

Retrieve Username

* required fields

 Search function is temporarily disabled and will be enabled at a future date when the database is populated

Email: *

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

Search ▾

Retrieve Password * required fields

Search function is temporarily disabled and will be enabled at a future date when the database is populated

Username: *

Email: *

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.

User Profile for [redacted] * required fields

✘ You must change your password.

When changing your password it must be 8-32 characters with at least one upper case letter, one lower case letter, one number and one of the following special characters [!, @, #, \$, %, &, +, ~].

Username: *

Current Password: *

New Password: *

Confirm 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:

The screenshot shows the GUDID (Global Unique Device Identification Database) interface. The header includes the GUDID logo and navigation links for 'About', 'User Guide', and 'Logout'. Below the header is a navigation bar with 'Home', 'Search', and 'Manage Accounts' options. The user is logged in as 'FDA COORDINATOR'. The main content area is titled 'User Profile for [redacted]' and includes a 'required fields' indicator. There are two tabs: 'User Details' (selected) and 'Change Password'. The 'User Details' form contains fields for 'First Name', 'Last Name', 'Email', and 'Phone', all marked with an asterisk to indicate they are required. Below these are 'Account Type' (set to 'COORDINATOR') and 'Organization' fields. 'Save' and 'Reset' buttons are located at the bottom right of the form.

Labeler Data Entry User

This screenshot is similar to the one above, showing the GUDID interface for a 'Labeler' user. The user is logged in as 'FDA LABELER'. The 'User Profile for [redacted]' page has the 'User Details' tab selected. The form fields for 'First Name', 'Last Name', 'Email', and 'Phone' are present and marked as required. The 'Account Type' is set to 'LABELER'. 'Save' and 'Reset' buttons are at the bottom right.

FDA PT Code

The screenshot shows the 'Find FDA Preferred Term Code' search interface. At the top, there is a navigation bar with 'Home', 'Search', and 'Manage DI' options. The user is logged in as 'FDA Terrell Suggs LABELER'. The main heading is 'Find FDA Preferred Term Code'. Below this is a search input field with a blue arrow pointing to it from the left. To the right of the input field are three buttons: 'Search', 'Clear', and 'Cancel'. A blue arrow points down to the 'Search' button.

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:

The screenshot shows a web interface for finding FDA Preferred Term Codes. At the top, there are navigation links for Home, Search, and Manage Accounts, along with the FDA Ray Rice COORDINATOR logo. Below this is a search bar with the text 'defibrillator' and buttons for Search, Clear, and Cancel. The search results are displayed in a table with columns for FDA PT Code, Term, and Definition. The second row is highlighted in blue, showing the code XNDZ for 'External defibrillator electrode pad'. The table also includes a 'View' dropdown set to 25, a record count of 25 / 63 records, and a pagination control showing page 1 of 3.

FDA PT Code	Term	Definition
XRVN	Resuscitation trolley, equipped	A cart designed to store/transport devices and supplies used in emergency resuscitation procedures. This trolley (cart) typically consists of a shelf/drawer cabinet-like structure on wheels that contains a defibrillator, electrocardiograph (ECG) monitor, pulmonary resuscitator, backboard for external cardiac compression, surgical supplies, drugs, and various other instruments and accessories necessary to initiate cardiopulmonary resuscitation (CPR).
XNDZ	External defibrillator electrode pad	A conductive medium designed to be used between the metal contact surface of an external defibrillator electrode, of the paddle-type, and the patient's skin. A defibrillator electrode pad is available in two basic designs: 1) a thickened conductive gel or polymer layer reinforced by a non-woven material; or 2) a conductive adhesive pad with a metal contact on its outer surface. This is a single-use device.
TKHP	Cardiac pulse generator test magnet	A magnetized device used to test an inhibited or triggered type of pacemaker or defibrillator, and cause an inhibited or triggered generator to revert to asynchronous operation. The device is placed on the outside of the patient's thorax over the pacemaker/defibrillator for analysis of the implanted device's function. The magnet will activate the magnet sensitive relay in the pacemaker/defibrillator and will change the function of the implanted device. It is possible to evaluate the function of the implanted device via an electrocardiograph.
RRQ7	Home automated external	A portable electronic device intended for use at home to automatically detect cardiac arrhythmias (ventricular fibrillation/pulseless ventricular tachycardia) in a sudden cardiac arrest (SCA) patient, after which it audibly/visually instructs an operator to enable it to activate defibrillation of the heart through application of electrical shocks to the

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.

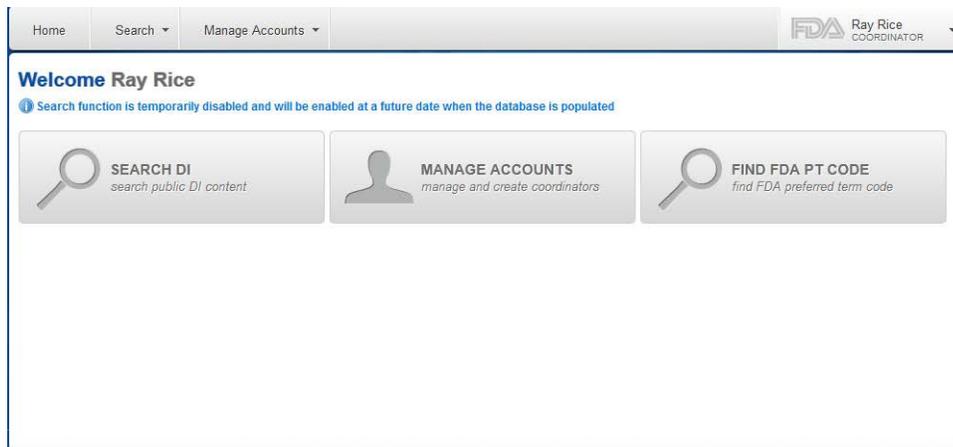


Note to system users: The GMDN is not a codeset owned by FDA. For any questions regarding GMDN Codes or how to access a full list of these terms, please contact the GMDN Agency at <https://www.gmdnagency.com/>

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

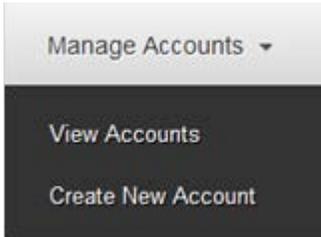


FDA PT Code allows a Coordinator to search for a GMDN Preferred Term or GMDN Definition, and retrieve the FDA assigned Preferred Term Code (See [FDA PT Code](#)) (The FDA PT Code is mapped to the GMDN code)

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**

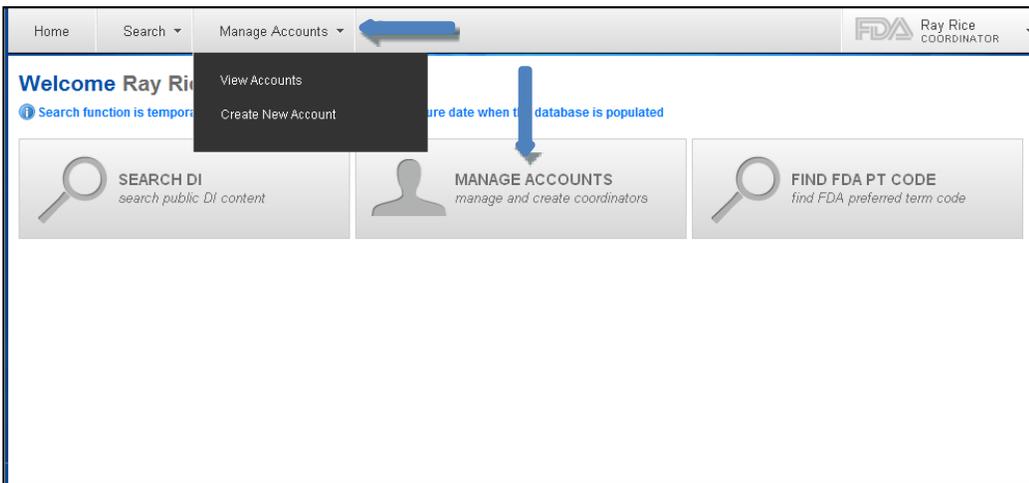
Access the Database

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.

Enter information. Click **Filter**. Results shown in table below.

Last Name: First Name: Username: Email: Status: Mode:

Account Type: DUNS #: Organization:

Labeler Data Entry

Filter Clear

View: 10 2/2 records

Click username to open an account.

Create new account Add New Account

Username	Last Name	First Name	Email	Account Type	Organization	Status	Mode	Password
bl_hfuser1	Bfuser1	LDE	...	Labeler Data Entry	Booz Allen & Hamilton Inc	Enabled	Activated	Reset
bl_hf_user1	LDE	P	terence.oe_1@...	Labeler Data Entry	Booz Allen & Hamilton Inc	Enabled	Activated	Reset

2/2 records, 1/1 page

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

Home Search Manage Accounts FDA Ray Rice COORDINATOR

Account Details for Suggs, Terrell

Enabled Activated Reset Password Save Reset Cancel

General Information

Account Type: *
Labeler Data Entry

Username: * First Name: * Last Name: * Email: * Phone: *
tsuggs Terrell Suggs terrell.suggs@fda.hhs.gov 0000000000

Organization Information

Organization DUNS #: * Organization Name:
053588527 Booz Allen Hamilton Inc.

Address 1: Address 2: City: State/Province: ZIP / Postal: Country:
1 Preserve Plow Ste 200 Rockville MD 208524279 USA

Labeler DUNS

<input checked="" type="checkbox"/>	DUNS #	Organization Name	Address	City	State/Province	ZIP/Postal	Country
<input checked="" type="checkbox"/>	053588527	Booz Allen Hamilton Inc.	1 Preserve Plow Ste 200	Rockville	MD	208524279	USA

Save Reset Cancel

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.

Home Search Manage Accounts FDA

Create New Account

Complete form. Click Save.

Account Type: *
Labeler Data Entry

Username: * First Name: * Last Name: * Email: * Phone: *

Organization Information

Organization DUNS #: 077369358

Organization Name:

Address 1: 12015 Lee Jackson Hwy Address 2: City: Fairfax State/Province: VA ZIP /Postal: 220333300 Country: USA

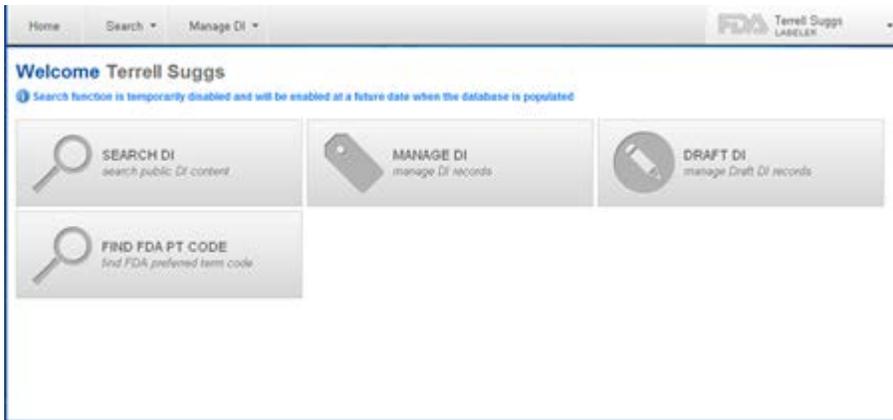
<input type="checkbox"/>	DUNS #	Organization Name	Address	City	State/Province	ZIP/Postal	Country
<input type="checkbox"/>	077369358		12015 Lee Jackson Hwy	Fairfax	VA	220333300	USA

Reset Cancel

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.

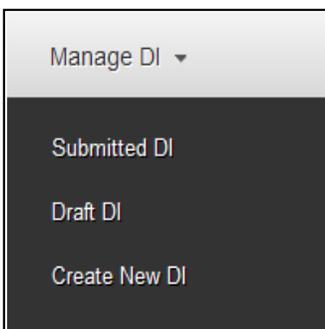
Note: This link is temporarily disabled and will be enabled when Public Search is made available.

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.

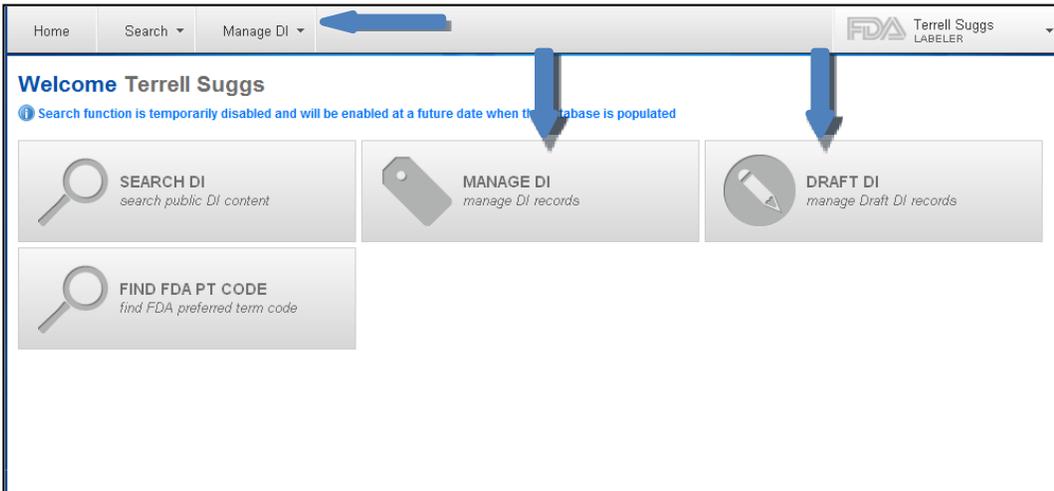
Draft DI Records



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.

The screenshot displays the 'Manage Device' interface. At the top, there are search filters for DI Number, Company Name, Brand Name, Version or Model Number, and DI Record Status. Below the filters is a table with the following data:

DI Number	Company Name	Brand Name	Version or Model Number	DI Record Status
02254883294002	Boyd Alton & Romatowski	top	version	Published
1523412342134342	Boyd Alton & Romatowski	400	test	Unpublished
00000000000000	Boyd Alton & Romatowski	400	test	Deactivated

The detailed view below shows the 'Device Identifier (DI) Record Details for Unpublished Record'. The status is 'Unpublished', indicated by a red dot. The 'Device Information' section includes the following fields:

- Issuing Agency: G01
- Primary DI Number: 1523412342134342
- Device Count: 2
- Shift of the DI Number: 44074054407405
- Labeler DURS Number: 07730338
- Company Name: Boyd Alton & Romatowski
- Company Physical Address: 12015 Lee Jackson Hwy, Fairfax, VA 220332200
- Brand Name: Test
- Version or Model Number: version
- Catalog Number: 152341332

The 'Device Description' field is currently empty.

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.

Device Identifier (DI) Record Details for New Record

Device Information

Device Identifier (DI) Information

Issuing Agency: [dropdown] Primary DI Number: [text] Device Count: [text] Unit of Use DI Number: [text]

Labeler DUNS Number: [text] Company Name: [text] Company Physical Address: [text]

Brand Name: [text] Version or Model Number: [text] Catalog Number: [text]

Device Description: [text area]

Commercial Distribution

DI Record Publish Date (mm/dd/yyyy): [text] Commercial Distribution End Date: [text]

Alternative and Additional Identifiers

Direct Marking (DM)

Device Subject to Direct Marking (DM), but Exempt

DM DI Different from Primary DI

DM DI Number: [text]

Package DI

Package DI Number: [text] Quantity per Package: [text] Contents ID Package: [text] Package ID: [text]

Support Contact

Support Contact Name: [text] Support Contact Email: [text]

Device Status

Human Cell, Tissue or Cellular or Tissue-Based Product (HCTIP) HCTIP Premarket

Device Exempt from Premarket Submission

FDA Product Code: [text]

FDA Listing

UDI Listing Number: [text]

GMDN

Code: [text] Name: [text] Structure: [text]

Device Characteristics

For Single Use: [checkbox]

Types of Production Identifiers

Controlled By Lot or Batch Number: [checkbox]

Controlled By Manufacturing Date: [checkbox]

Controlled By Serial Number: [checkbox]

Later Information

Device required to be labeled as containing natural rubber latex or other natural rubber (21 CFR 801.402)

Device labeled as "Not made with natural rubber latex"

Published DI Record:
Publish Date =< today,
available via Public Search

Unpublished DI Record:
Publish Date >= today, not
available via public search.

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.

The screenshot displays the 'Device Identifier (DI) Record Details for Published Record' page. At the top left, the status is 'Published' with a green checkmark. A blue arrow points to the 'View History' link. On the top right, there are 'Copy', 'Edit', and 'Cancel' buttons. A tooltip over the 'Edit' button reads: 'View or copy the existing DI. Click View History for DI record history.' The form contains the following fields:

Device Identifier (DI) Information			
Issuing Agency: *	Primary DI Number: *	Device Count: *	Unit of Use DI Number:
GS1	02394803294802	4	44674654567456
Labeler DUNS Number: *	Company Name:	Company Physical Address:	
077369358		12015 Lee Jackson Hwy, Fairfax, VA 220333300	
Brand Name: *	Version or Model Number: *	Catalog Number:	
Test	version	12341432	
Device Description:			
Commercial Distribution			
DI Record Publish Date (mm/dd/yyyy): *	Commercial Distribution End Date (mm/dd/yyyy):	Commercial Distribution Status:	
07/03/2013	07/24/2013		

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

Home Search Manage DI FDA

Manage Drafts

DI Number: Company Name: Brand Name: Version or Model Number:

Filter Clear

View: 10 2 / 2 records, 1 / 1 page New DI

DI Number	Company Name	Brand Name	Version or Model Number	Purge Date	Remove
09992292929998	Blue Wave In Healthcare Inc	Test	1234567890	07/04/2013 09:56 PM	Remove
436543210987654	Blue Wave In Healthcare Inc	Test	1234567890	06/30/2013 03:54 PM	Remove

2 / 2 records, 1 / 1 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.

Home Search Manage DI FDA

Device Identifier (DI) Record Details for Draft Record

Save Draft Delete Draft Review Cancel

Device Information

Device Identifier (DI) Information

Issuing Agency: * 651 Primary DI Number: * 09992292929998 Device Count: * 4 Unit of Use DI Number: 44674654567456

Labeler DUNS Number: * 0773693 Company Name: Company Physical Address: 12015 Lee Jackson Hwy, Fairfax, VA 220333300

Brand Name: * Test Version or Model Number: * 1234567890 Catalog Number: 12341432

Device Description:

Commercial Distribution

DI Record Publish Date (mm/dd/yyyy): * 07/03/2014 Commercial Distribution End Date (mm/dd/yyyy): 07/24/2014 Commercial Distribution Status:

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.

Device Identifier (DI) Record Details for Published Record

Published [View History](#)

Copy **Edit** **Cancel** * required fields

Device Information

Device: [View History](#) Information

Issuing Agency: IBCC	Primary DI Number: rekp9345hg8h45gulhulwr	Device Count: *	Unit of Use: View History
Labeler DUNS Number: 80170941	Company Name:	Company Physical Address: 3015 Dent Pl MALDEN, MA 02148	
Brand Name: tes		Version or Model Number: ts	Catalog Number:



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.

4.2 GUDID Sample Record of an Unpublished Record

4.2.1 Creating a New DI Record

The screenshot displays the GUDID (Global Unique Device Identification Database) interface for creating a new Device Identifier (DI) record. The page title is "Device Identifier (DI) Record Details for New Record" and it includes a "Printer Friendly" link and buttons for "Save Draft", "Review", and "Cancel". The form is titled "Device Information" and contains the following fields:

- Issuing Agency:** A dropdown menu with "1015000" selected.
- Primary DI Number:** A text input field containing "1234567890123456".
- Device Count:** A text input field containing "1".
- Unit of Use DI Number:** An empty text input field.
- Labeler DUNS Number:** A dropdown menu with "1015000" selected.
- Company Name:** A text input field containing "Safeway Grocery".
- Company Physical Address:** A text input field containing "4551 Forbes Blvd, Landover, MD 207064389".
- Brand Name:** A text input field containing "CompuHyper GlobalMed Ultra Implantable".
- Version or Model Number:** A text input field containing "123456".
- Catalog Number:** A text input field containing "123456".
- Device Description (max 2000 characters):** A text area containing "A made up device for creating this 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.

Publish date could be set in future

DI Record Publish Date (mm/dd/yyyy): *

Commercial Distribution End Date (mm/dd/yyyy):

Commercial Distribution Status:

Alternative and Additional Identifiers

Direct Marking (DM)

Device Subject to Direct Marking (DM), but Exempt

DM DI Different from Primary DI

DM DI Number:

Secondary DI

[Add Secondary DI](#)

Issuing Agency	Secondary DI Number	Action
No secondary device identifiers currently defined		

Package DI

[Add Package DI](#)

Package DI Number	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status	Action
No package device identifiers currently defined						

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

Customer Contact		
		 Add Customer Contact
Customer Contact Phone	Customer Contact Email	Action
8005551234	xxx@xx.xx	 
+15555551234	xxx@xx.xx	 

For entering Customer Contact information click on Add Customer Contact

- Enter Customer Contact Phone. If there is no phone number please enter 999-999-9999
- 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"

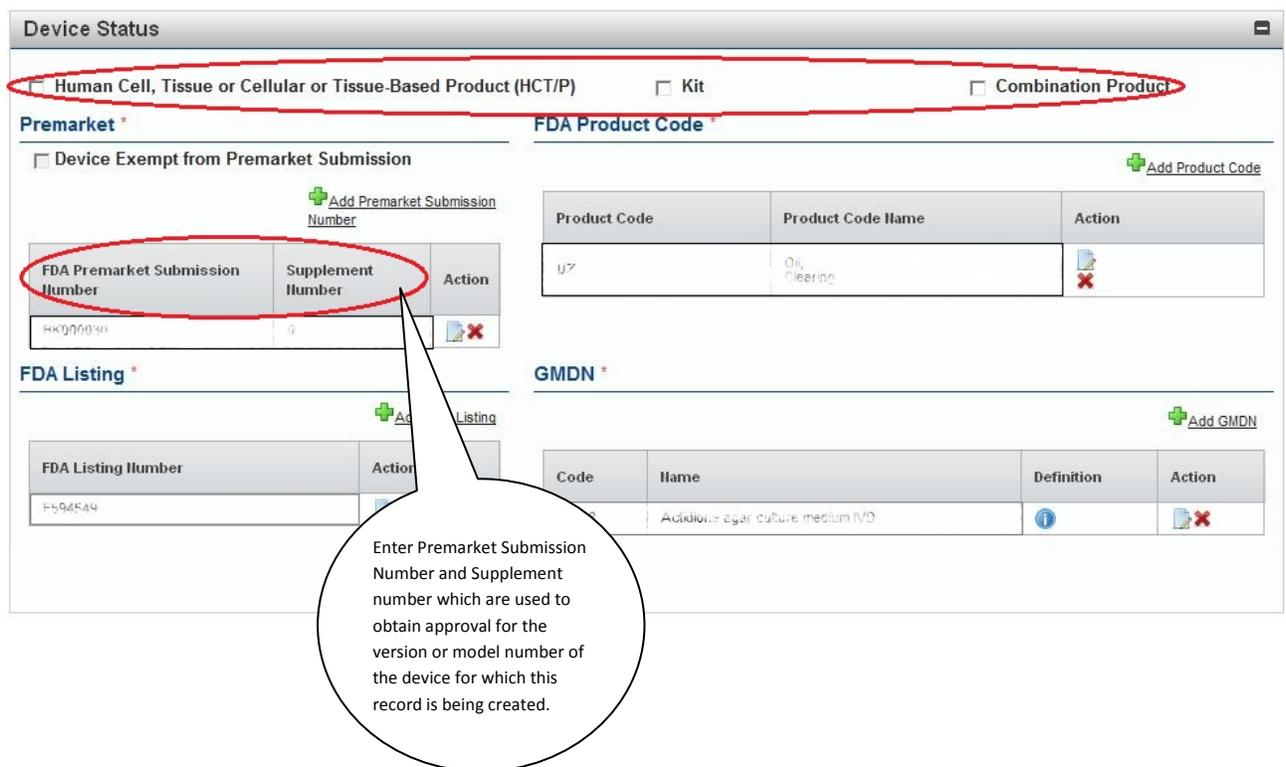


Figure 4 Screenshot of GUDID interface

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

Size Type Text	Action
Length: 8 Millimeter	
Length: 2.25 Millimeter	

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

The screenshot displays the GUDID interface with two main sections: "Storage and Handling" and "Sterilization".

Storage and Handling: A table lists storage information. One entry is "Storage Environment Temperature: less than 45 Degrees Celsius", which is circled in red. An "Action" column with a delete icon is visible.

Sterilization: Two dropdown menus are present: "Device Packaged as Sterile: *" with "Yes" selected (circled in red), and "Requires Sterilization Prior to Use: *" with "No" selected. Below is a table for "Sterilization Method" with the text "No sterilization method currently defined".

Footer: Status indicators show "Activated" (green) and "Unpublished" (red, circled in red). Links for "View History" and "Printer Friendly" are present. "Review" and "Cancel" buttons are at the bottom right, with "Review" circled in red.

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.