

Global Unique Device Identification Database (GUDID)

Guidance for Industry and Food and Drug Administration Staff

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For questions for the Center for Devices and Radiological Health regarding this document contact UDI Regulatory Policy Support, 301-796-5995, email: udi@fda.hhs.gov. For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research**

Preface

Public Comment

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Global Unique Device Identification Database (GUDID)

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

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 the 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, we 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 24, 2013. UDI initiatives are also underway globally -- the European Commission released a framework for a UDI System in April 2013; the International Medical Device Regulators Forum (IMDRF) UDI Work Group issued a guidance document on UDI in December 2013.

This document is primarily intended for device Labelers¹, and provides information necessary for submitting data to the Global Unique Device Identification Database (GUDID). A draft version of this document was

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

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released on September 24, 2013 with a 60 day comment period, which ended on November 25, 2013. More than 300 comments were received from 21 entities. In order to provide labelers access to the latest information as soon as it is available, and address sections that received the most comments and questions, sections of this document were previously finalized and released on June 11, 2014. This current iteration of the document finalizes the remaining sections and incorporates sections finalized earlier, in order to provide one complete and final document.

Please note that database enhancements may 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. We intend to periodically update this document to reflect system changes and enhancements.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, a guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2 Unique Device Identifier (UDI)

The “unique device identifier” (UDI) should be created and maintained by device labelers based on global device identification standards managed by FDA-accredited Issuing Agencies^{2,3}. As of the publication date of this document, we have accredited three issuing agencies – GS1, HIBCC and ICCBBA. The ‘UDI Formats by FDA Accredited Issuing Agency’⁴ document, provides the standard UDI formats for the three issuing agencies.

A UDI is required to appear on the label of every medical device, and every device package, unless excepted. This includes combination products that contain a device constituent part; convenience kits; *in vitro* diagnostic products; human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated as devices; and stand-alone software⁵. The UDI is composed of two parts:

- Device Identifier (DI) - a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device; and
- Production Identifier(s) (PI) – a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device, unless excepted:
 - the lot or batch number within which a device was manufactured;
 - the serial number of a specific device;
 - the expiration date of a specific device;
 - the date a specific device was manufactured;
 - and, for an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c)⁶.

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 Refer to the UDI Final Rule (<http://www.fda.gov/udi>) for details on issuing agencies and their role in UDI assignment.

³ See 21 CFR 801.57(c) and visit <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/ucm161456.htm> for information regarding continued use of National Health Related Items Code (NHRIC) and National Drug Code (NDC).

⁴ See “UDI Formats by FDA-Accredited Issuing Agency” document, available on www.fda.gov/udi

⁵ Stand-alone software version number may be represented as Lot or Batch number production identifier.

⁶ 21 CFR 1271.290(c) requires that the manufacturer of each HCT/P assign and label the HCT/P with a distinct identification code that allows the manufacturer to relate the HCT/P to the donor and to all records pertaining to the HCT/P. The distinct identification code may take the form of a donation identification number, serial number, lot number, or a combination of these production identifiers. In

Therefore, **UDI = DI + PI**.

The DI will serve as the primary key and can be used to look up information about the device in the GUDID.

Any identifiers beyond those specified in this document are outside the scope of the FDA regulated UDI.

Note that the UDI of a class I device is not required to include a PI. Further, a class I device that bears a Universal Product Code (UPC) on its label and device packages is deemed to have met the UDI labeling requirements. Finally, Class I devices that FDA has by regulation exempted from the good manufacturing practice requirements (other than recordkeeping requirements) do not need a UDI. See 21 CFR 801.30(a)(2).

Labelers are required to enter the DI along with additional device attribute information to the GUDID, as specified in the final rule, unless subject to an exception or alternative. While we expect GUDID DI submissions to occur as soon as practicable, for device versions or models initially entering commercial distribution, the DI records for such devices should be in the published state no later than fifteen calendar days from the initial date that version or model is introduced into commercial distribution.

3 Global Unique Device Identification Database (GUDID)

The GUDID serves as the repository of key device identification information. The GUDID contains ONLY the DI, which serves as the primary key to obtain device information in the database. PIs are not submitted to or stored in the GUDID; the GUDID contains only production identifier flags to indicate which PI attribute(s) are on the device label, unless excepted.

The GUDID includes all of the data elements required by 21 CFR 830.310. The GUDID also includes certain ancillary administrative data used to develop and maintain the GUDID and to facilitate integration of DI information with internal FDA systems. A complete list of GUDID data elements and descriptions are provided provided in the ‘GUDID Data Element Reference Table’⁷. For those data attributes in the GUDID that appear in medical device labeling, the attribute values submitted to GUDID should be consistent with their representation in the labeling. See example in *Appendix D*, which maps some GUDID attributes to a fictitious device label.

The design principles guiding GUDID development includes the following:

- Standards-based submission with two options:
 - Structured input via the GUDID Web Interface – requires manual data entry and is geared for low volume submitters.
 - Health Level 7 (HL7)⁸ Structured Product Labeling (SPL)⁹ submission via the FDA Electronic Submissions Gateway (ESG)¹⁰ – allows for submission via xml files and is geared for high volume submitters.

the GUDID, labelers of HCT/PIs regulated as medical devices should select the appropriate type of production identifier that appears the label of the device.

⁷ See GUDID Data Elements Reference Table, available on www.fda.gov/udi

⁸ HL7 is a standards development organization, whose mission is to provide messaging standards for interoperability, exchange, management, and integration of data that supports clinical patient care and the management, delivery, and evaluation of healthcare services. Visit <http://www.hl7.org> for more information.

⁹ Structured Product Labeling (SPL) is a HL7 standard for the exchange of product information using extensible markup language (XML).

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- Standards-based data repository with controlled vocabularies including:
 - Dun & Bradstreet (D&B) Number (DUNS)¹¹
 - Global Medical Device Nomenclature (GMDN)¹²
 - FDA Product Codes
- Free and public access to the device information in GUDID via public search; download capability is planned for the future.

3.1 GUDID Key Concepts

The next few sections present an overview of GUDID key concepts such as GUDID account and user roles, the device identifier record, and the device identifier record life-cycle. Note that these concepts apply to both GUDID submission options – Web Interface and HL7 SPL xml file submission.

3.1.1 GUDID Account

Labelers that are required to submit information to the GUDID should first request a GUDID account. This section presents an overview of the GUDID account, the user roles, preparatory steps to obtain a GUDID account, how to request a GUDID account and how to manage account changes. The structure of the GUDID Account and the different user roles are depicted in Figure 1.

¹⁰ FDA ESG enables the secure submission of regulatory information. For more information, please visit: <http://www.fda.gov/esg>

¹¹ Data Universal Numbering System or D-U-N-S® Number is a unique nine-digit identification number assigned and managed by Dun & Bradstreet to business entities. For more information, visit <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162544.htm>

¹² Global Medical Device Nomenclature (GMDN) is system of internationally agreed descriptors used to identify medical device products and is managed by the GMDN Agency. Visit: <http://www.gmdnagency.com/default.aspx>

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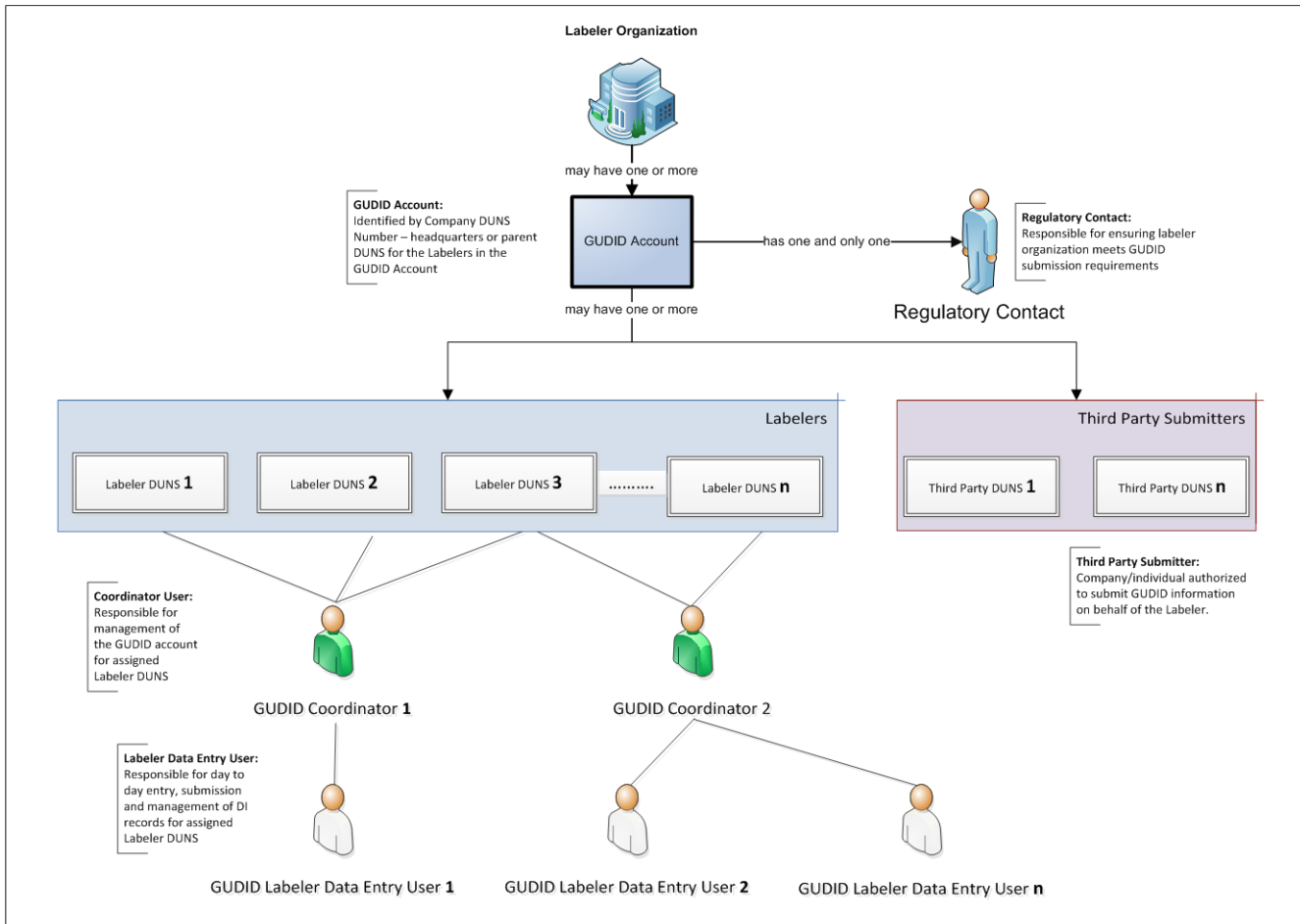


Figure 1: GUDID Account and User Roles

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A Labeler Organization may have one or more GUDID accounts.

- GUDID utilizes DUNS numbers to enable identification of labeler organizations using a uniform standard and process. The DUNS number is an important component of the FDA Unique Facility Identifier System, along with a Geocode, which specifies the exact location of the facility (GUDID does not collect Geocodes).
- Labelers should manage their company information via the DUNS number and GUDID pulls company name and address from the D&B DUNS database.
- Each GUDID account is identified by the Organization DUNS Number.
 - This DUNS number represents the labeler's view of the highest corporate level in the labeler organization; it may be the headquarters DUNS number, or the parent DUNS number for the labelers included in the GUDID account.
 - Please ensure that the name and address in the D&B DUNS database is accurate, as this number is used to identify the labeler organization in GUDID; company name and address are pulled from the DUNS database.
 - The organization DUNS number serves as the primary key for the GUDID account. Once used, it cannot be reused to create another GUDID account.
 - The organization DUNS number can be used as a Labeler DUNS number (see below).
- Each account should have only one Regulatory Contact.
 - As noted in 21 CFR 830.320(a), a Regulatory Contact¹³:
 - Is the individual who serves as the point of contact to us on matters relating to the identification of medical devices marketed by the labeler; he/she is responsible for ensuring the labeler organization meets GUDID submission requirements.
 - Is the highest point of contact for the labeler organization, i.e., we may first contact the GUDID Coordinator for issues related to the data submitted to GUDID, and if the issue is not resolved, bring it to the attention of the Regulatory Contact.
 - Does not have functional user role in GUDID i.e, no user-name or password to access GUDID.
 - Can also serve as GUDID Coordinator and Labeler Data Entry user, if so desired (see below); both of these user roles would have a separate user name and password to access GUDID.
 - You may choose to use a third-party to serve as the Regulatory Contact for GUDID as described in 21 CFR 830.320(a); you should inform us of your intent to do so during the GUDID account request process via a letter on your company letterhead, signed by a responsible official from your organization.
- Each GUDID account should have one or more labelers, identified by Labeler DUNS numbers.
 - Device information would be submitted for the Labelers identified in the GUDID account.
 - Each device record should be associated to a Labeler DUNS number, and is used to pull the labeler company name and address from the D&B DUNS database.
 - To ensure data consistency the company name associated to the Labeler DUNS number should match the company name that appears on the device label. Ideally the address associated with the DUNS number should also match the address on the device label, but since address is not displayed to the GUDID public user, this is not a requirement; however, labelers are encouraged

¹³ GUDID Account user contact information provided is for FDA internal use only; not available via GUDID public search and retrieval.

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to work towards this model for new products and when making changes to existing products as appropriate.

- Organization DUNS number can be used as Labeler DUNS number.
- Labeler DUNS number, once used, cannot be reused in any other GUDID account.
- Each GUDID account should have one or more Coordinators¹³.
 - Each Coordinator would be assigned one or more Labeler DUNS numbers, in a given GUDID account.
 - Coordinators manage the GUDID account for their designated Labeler DUNS numbers. Responsibilities should include:
 - Create Labeler Data Entry (LDE) User account(s) (see below).
 - Assign Labeler DUNS number(s) to LDE(s).
 - Create LDE User role for a third-party (see below), if so desired.
 - Serve as Regulatory Contact, if so desired.
 - Serve as LDE user, if so desired; separate user name and password is provided for the LDE user role.
 - Serve as the first point of contact and respond to FDA inquiries related to GUDID data quality, incorrect or inconsistent data, and other submission/data specific questions.
 - A given Labeler DUNS Number can be assigned to more than one Coordinator (see Figure 1, Labeler DUNS Number 3 is assigned Coordinator 1 and Coordinator 2). The Coordinators would then share responsibility for DI records associated to that Labeler DUNS number.
- Each GUDID account should have one or more LDE Users¹³.
 - Each LDE user is assigned one or more labelers, identified by Labeler DUNS numbers, in a given GUDID account.
 - An LDE user:
 - Is responsible for data entry, submission, and management of device identification information for their designated Labeler DUNS into the GUDID.
 - Can serve as Regulatory Contact, if so desired.
 - Can serve as Coordinator user, if so desired; separate user name and password is provided for the Coordinator user role.
 - A given Labeler DUNS Number can be assigned to more than one LDE user. The LDE users would then share responsibility for DI records associated to that Labeler DUNS number.

The labeler has the option to designate third-party submitters for GUDID submissions. A third-party submitter is a company/individual (contractor, vendor) authorized to submit GUDID information on behalf of the labeler. The third-party may submit data on behalf of the labeler, but the labeler is ultimately held responsible for the information submitted to GUDID.

- Each GUDID account may have zero or more third-party submitters.
- Web Interface submission option – a third-party may use the GUDID Web Interface to enter data for the labeler. You, the labeler, may choose to request the Coordinator user role for the third-party (request sent to FDA, see section 3.1.1.2); you may provide the third-party with LDE user access.
- HL7 SPL submission option – the third-party may:
 - Provide software solution/tool to generate the HL7 SPL xml file; you, the labeler, would then submit the file via the FDA ESG. or,
 - Provide end-to-end solution to the labeler, i.e., generate the HL7 SPL xml file, and submit it via the FDA ESG for the labeler. In order to enable a third party to submit to GUDID via the ESG, the following should be noted:

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- You, the labeler, should identify the third-party by providing the third-party DUNS number during your GUDID account request. The third party is associated to your labeler account. By identifying the third-party, you are authorizing the third-party to submit GUDID information on your behalf.
- GUDID HL7 SPL submissions sent via the ESG by a third party not associated to a GUDID account are rejected.

Note that GUDID Regulatory Contact, Coordinator and LDE user contact information provided by labeler organizations is used for internal FDA purposes only; not available via GUDID public search and retrieval.

Submission of device information to GUDID requires establishment of a GUDID account, regardless of the submission option chosen –via Web Interface or via FDA ESG as HL7 SPL xml files. Please note that the GUDID account is not by submission type, i.e., a separate GUDID account is not needed for each submission option. The account identifies the labeler in GUDID and enables submission of device information via both options. See section 3.1.1.2 for detailed description of the account establishment process.

Search and retrieval of GUDID information does not require a GUDID account.

3.1.1.1 Preparatory Steps Prior to Requesting a GUDID Account

Prior to requesting a GUDID account, labeler organizations are encouraged to ensure the following:

- Familiarize yourself with the two submission options available – GUDID Web Interface and HL7 SPL xml file submission.
- Identify the DUNS Numbers to be used for your GUDID account.
 - If your company does not have a DUNS number, you can obtain one free of charge from D&B. Please note that this may take up to 30 business days; please plan accordingly.
 - Expedited options to obtain a DUNS number are available for a nominal fee.
 - Please visit <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162544.htm> for more information.
- Ensure the company name and address associated to the DUNS number is correct; if any changes are necessary, please update your information in the D&B DUNS database before requesting a GUDID account.
- Identify individuals for the various user roles in GUDID -- Regulatory Contact, Coordinator(s) and LDE user(s).
 - Note that the one individual can take on multiple GUDID user roles.
 - If you plan to use a third-party to serve as the Regulatory Contact for GUDID as described in 21 CFR 830.320(a), please inform us of your intent to do so during the GUDID account request process via a letter on your company letterhead, signed by a responsible official from your organization.
- Identify an individual to request the GUDID account; and, once the account is established, to manage all account changes.
- Identify third-party submitters, if applicable.
 - Obtain third-party DUNS number after ensuring that they have verified their information in the DUNS database as accurate.

3.1.1.2 GUDID Account Request Process

Once the necessary information is gathered, a GUDID account request may be submitted to us. Visit <http://www.fda.gov/udi> for information on how to submit the request.

The following information should be provided when requesting a GUDID Account:

- Labeler Organization DUNS Number – this DUNS number represents the labeler’s view of the highest corporate level in the labeler organization; it may be the headquarters DUNS number, or the parent DUNS number for the Labelers included in the GUDID account.
- Labeler Organization Name – this is used for verification purposes only; GUDID obtains company name and address from the D&B DUNS database.
- Regulatory Contact information – name, email, phone, physical address.
- Labeler DUNS for the GUDID Account – as indicated earlier in Section 3.1.1, the company name associated to the Labeler DUNS number should match the labeler name as it appears on the device label; ideally, the company address associated to the DUNS number should also match the address on the label, but since address is not displayed to the GUDID public user, this is not a requirement for data consistency.
- Coordinator Information:
 - Contact information – name, email, phone
 - List of Labeler DUNS that is the responsibility of the Coordinator; if there are multiple Coordinators, please specify the DUNS that each Coordinator is responsible for in GUDID.
- Third-party DUNS numbers, if applicable
- Indicate the preferred submission option – Web Interface or HL7 SPL or both
 - HL7 SPL submitters should first complete testing as specified in the HL7 SPL Implementation specification, prior to submitting to production GUDID. Therefore, HL7 SPL submitters are first provided with a test GUDID account.

Note that GUDID Regulatory Contact, Coordinator and LDE user contact information that you provide is used for internal FDA purposes only; not available via GUDID public search and retrieval.

Once we receive the GUDID account request, the information is reviewed. We may contact the individual requesting the account with any questions such as discrepancies with labeler company name and address associated to DUNS numbers, third party information etc.. Once all issues are resolved, we create the GUDID account using the GUDID Web Interface; the Coordinator receives login information and a temporary password via a system generated email.

Each GUDID account will have, at a minimum:

- one Regulatory Contact
- one Labeler DUNS number
- one Coordinator – for submitters who are using the HL7 SPL submission option, the Coordinator user is optional.

Once a GUDID account is created:

- The Web Interface submitter may login and begin using GUDID¹⁴.

¹⁴ For detailed information on logging in and using GUDID for each user role, please refer to the Global Unique Device Identification Database (GUDID) User Manual, available at --

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- Coordinator may access the system via their temporary login and password to create LDE Users
- Coordinator should have the following information to create an LDE user account:
 - LDE user information: name, email, phone
 - List of labeler DUNS to be assigned to the LDE user
- Once accounts are created, the LDE user receives temporary login and password via system generated email.
- HL7 SPL ONLY submitters, please refer to section 3.2.2 for additional details.

3.1.1.3 GUDID Account Changes

To make changes to an existing GUDID account, please contact the FDA UDI Help Desk by visiting www.fda.gov/udi. We recommend that you identify an individual in your organization to manage GUDID account changes.

Account changes may include:

- Update Regulatory Contact information
- Add/update Coordinator information
- Change assignment of Labeler DUNS to Coordinators
- Add Labeler DUNS
- Add/update third-party submitter information
- Account changes related to mergers/acquisitions that may impact DI records – current version of GUDID has not implemented capability to handle all use-cases surrounding mergers/acquisitions. We are actively working to identify requirements for future system implementation. We request that you please contact us if you anticipate a merger/acquisition that may impact your DI records, so we can work proactively to address your situation.

3.1.2 Device Identifier (DI) Record

Recall from Section 2, that a UDI = Device Identifier (DI) + Production Identifier (PI).

The DI, together with associated data attributes¹⁵, constitutes a DI Record in the GUDID, and contains identifying information for a particular device version or model. Please note that information presented in this section applies to both GUDID submission options – Web Interface and HL7 SPL xml file submission.

The following are key characteristics of a DI Record in GUDID:

- GUDID will only contain the DI; the PI is never part of the GUDID. However, the GUDID will contain production identifier *flags*, to indicate which PI attribute(s) (lot or batch number, serial number, expiration date, manufacturing date and donation identification number) appear on the label of the device, unless excepted.
- Primary DI: Each DI record will have a Primary DI, which is the primary key for the record. This is the DI of the lowest level of a medical device package containing a full UDI. The lowest packaging level is also the base package.

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396841.pdf>

¹⁵ See GUDID Data Elements Reference Table, available on www.fda.gov/udi for a list of data attributes

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- Under 21 CFR 830.40(a), a version or model of a device may be identified using only one DI from a given FDA accredited issuing agency. The same version or model may be identified by UDIs from other FDA accredited issuing agencies; labelers must identify the DI from one issuing agency as the Primary DI in GUDID and the DIs from other issuing agencies may be listed as Secondary DIs (see below).
- The DI record may also contain additional device identifiers:
 - Secondary DI: An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different FDA accredited issuing agency than the primary DI.
 - Unit of Use DI: A virtual identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient when a base package contains more than one device. The package configuration example in *Appendix A*, Figure 1, includes a Unit of Use DI.
 - Direct Marking DI: An identifier that is permanently marked directly on the medical device; can be the same as or different from the Primary DI; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.
 - Package DI: A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers¹⁶).
 - Package information for a particular version or model of a device is part of the DI record. See section 3.1.2.1 below for more information.

Note that the current implementation of GUDID does not include the ability to capture the previous DI as required under 21 CFR 830.310(b)(2). This may be included in a future implementation of GUDID. Labelers will be provided sufficient notice and time to incorporate changes into their source systems.

- All DIs will be checked for uniqueness in the GUDID. Once used, a DI can never be reassigned to another device, even if the original device is no longer in commercial distribution.
 - When *Commercial Distribution End Date* <= today (i.e. today or a date in the past), the device will be considered no longer held or offered for sale by the labeler. The device may or may not still be available for purchase in the marketplace.
 - The device will still be in the database and available via public search, but will be noted as “*Not in Commercial Distribution*”.

Each DI record will be subject to GUDID business rules to ensure data quality. GUDID business rules for each data attribute are provided in the GUDID Data Elements Reference Table, available on www.fda.gov/udi.

Business rules include the following:

- Required data attributes must be provided – see GUDID Data Elements Reference Table, available on www.fda.gov/udi for a list of required attributes. While some fields in GUDID are not required, we recommend that labelers populate all fields applicable to the device, when the information is available in device labeling. For example, while *Device Description* is not required in GUDID, if you populate this attribute, users will benefit from the information.
- Validation of specified attributes. For example, the FDA Listing Number provided must be valid.
- Data constraints on specified attributes. For example, *Publish Date* must always be >= today (i.e., today or a date in the future).

¹⁶ The UDI Final Rule defines a Shipping Container as a container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another.

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- System rules that determine available user actions based on the status of the DI record. For example, only Unpublished and Published DI records can be copied. Sections 3.1.3.1 and 3.2.1.1 provide system rules for each DI record state.

3.1.2.1 Package Information in GUDID

According to 21 CFR 801.3, a device package is a fixed quantity of a particular version or model of a device. In order to adequately identify a device throughout distribution and use, the various package configurations, i.e. each different type of package, must have a unique identifier, 21 CFR 801.20(a)(2). Thus, if a device is sold in individual device packages, that are sold in boxes of thirty (30) device packages, that are sold in cartons that contain twelve (12) boxes of thirty (30) device packages, a different DI would be required to appear on the individual device package, on the box of thirty packages, and on the carton of twelve boxes of thirty device packages.

Following are key points to note regarding package information in GUDID:

- The Primary DI number for a DI record identifies the lowest level of medical device package containing a full UDI; also known as the base package. The Primary DI, therefore, is also the base package DI.
- The Device Count attribute provides the number of medical devices in the base package.
- Package configurations of the base package are part of the base package DI record.
- Package configurations inherit base package attribute values. Therefore, Package DIs do not need their own DI record; instead package information may be entered in the Package DI section of the Primary DI record for that device. Attributes specific to each package may be entered and include:
 - Package Device Identifier – DI for the particular package configuration (does not include shipping containers).
 - Contains DI Package –DI for the lower level package configuration contained within that particular package configuration (what is the DI for the package inside this package?).
 - Quantity per Package – number of packages contained within the particular package configuration with a unique DI (how many packages are inside this package?).
 - Package Type – optional text to describe the outer packaging of the product (box, carton, etc.) and enables users to understand higher-level packaging configurations.
 - Package Discontinue Date – indicates the date a particular package configuration is discontinued by the labeler.
 - Package Status –indicates whether the package configuration is in commercial distribution as defined under 21 CFR 807.3(b); auto-populated by the system based on Package Discontinue Date:
 - If *Package Discontinue Date* > today (i.e., a date in the future) or null, then *Package Status* = “In Commercial Distribution”
 - If *Package Discontinue Date* ≤ today (i.e., today or a date in the past), then *Package Status* = “Not In Commercial Distribution”

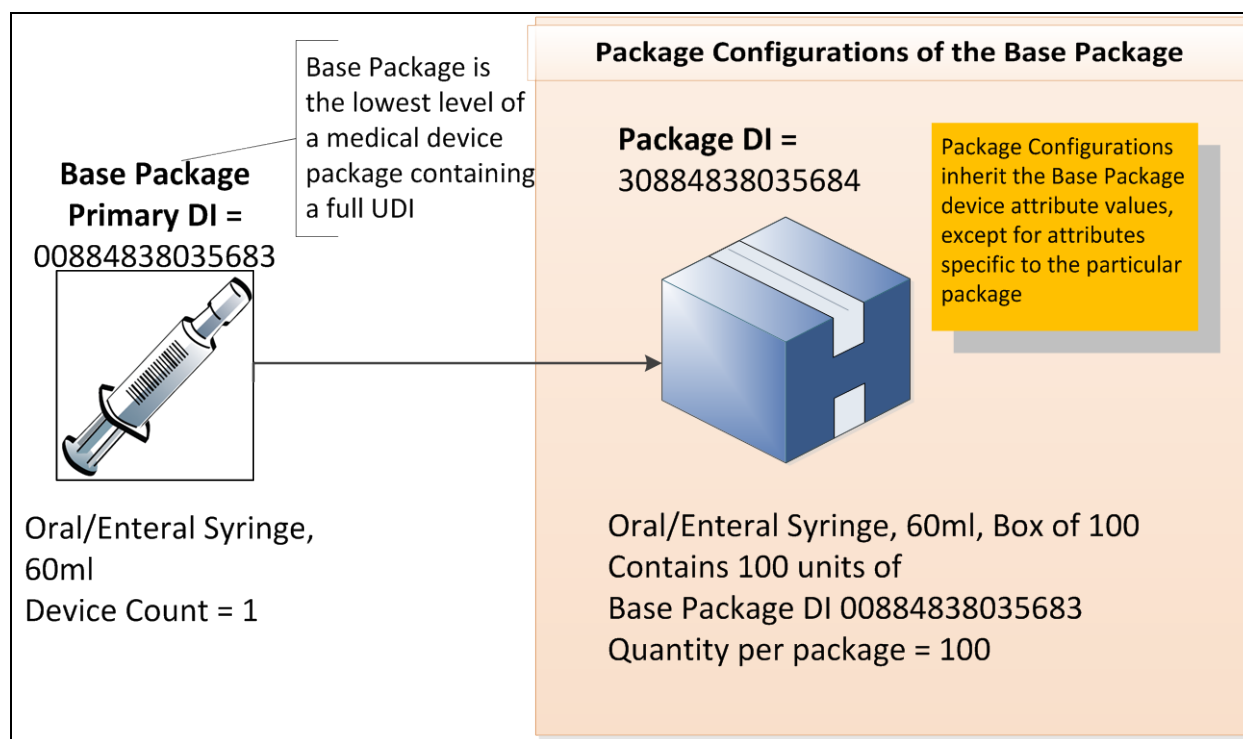
Figure 2 provides a package configuration example for GUDID where the DI is on the individual device with one package level.

- Oral/enteral syringe, each with Primary DI 00884838035683 and *Device Count* = 1.
- Box of 100 syringes, with Package DI 30884838035684 (contains 100 units of Primary DI 00884838035683).

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- *Package Discontinue Date* is blank (null); therefore *Package Status* is set to “In Commercial Distribution.”

Package 30884838035684 inherits all attribute values of base package 00884838035683, except for the attributes specific to 30884838035684, as shown in the table below.



Base Package

Primary Device Identifier	Device Count
00884838035683	1

Package Information

Package DI	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status
30884838035684	100	00884838035683	Box		In Commercial Distribution

Figure 2: Package Configuration Example¹⁷

Additional examples of package configurations, along with attribute values pertinent to packages, are provided in *Appendix A*.

3.1.2.2 Global Medical Device Nomenclature (GMDN)

Each DI record in GUDID requires entry of at least one GMDN Preferred Term (PT) codes. The GUDID business rules allow more than one GMDN term to be assigned per DI record, but this allowance was developed for the rare occurrence where more than one term is needed to accurately describe the device. It is expected that most records would assign one, and only one, GMDN term.

¹⁷ Device Identifiers used in the example are fictitious. Please refer to “UDI Formats by FDA Accredited Issuing Agency” in Appendix C for correct format of the DI numbers by FDA Accredited Issuing Agencies

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GMDN is a system of internationally agreed upon descriptors used to represent common device types for the purposes of grouping or categorization. GMDN terms, managed by the GMDN Agency, have been developed over the past 20 years as a vocabulary that represents the whole medical device arena, including such specialties as dental products, laboratory equipment, in vitro diagnostics, and biologic devices with cellular or tissue origins. Each GMDN Preferred Term (PT) has 3 components: Preferred Term Code (5-digit number), Preferred Term Name, and Preferred Term Definition. GMDN is maintained and updated to represent the evolving medical device field; meaning PT names and Definitions may be edited, new terms may be developed and out-dated terms may be made obsolete.

The GUDID represents the first implementation of the Global Medical Device Nomenclature (GMDN) within FDA. To obtain access to the GMDN vocabulary and to select GMDN terms for submission to the GUDID, companies should first become a member of the GMDN Agency. Visit <http://www.gmdnagency.com> for details. While GMDN Membership is not required (see ‘GUDID Search Module’ below), the GMDN Agency offers benefits and services with its Codes that aren’t available through the free-access GUDID search module.

Prior to submission of DI records to the GUDID, ensure the following:

- Identify and obtain appropriate GMDN terms for devices requiring GUDID submission.
- NOTE: if a device requires the development of a new device category, or a new Preferred Term, this requires time, so please plan accordingly.
 - When selecting a GMDN term, be advised that GMDN Definitions may contain language with a specific regulatory definition or implication to FDA. Assignment of a GMDN term with such language in the name or definition to your DI record does not imply agreement by FDA to a particular regulatory interpretation for your device.
- If your company has GMDN terms that are currently in use, use the GMDN Agency as a resource to evaluate the following:
 - Term fitness – determine if this GMDN term or device category best represents the device
 - Term Status -- determine if terms are “active” or have been made “obsolete”
 - If your company’s Codes have been designated as “obsolete,” identify replacement terms by searching the GMDN vocabulary or contacting the GMDN Agency for assistance.
 - NOTE: GMDN terms accepted by other regulatory authorities may not be acceptable terms for GUDID DI record submission. The GUDID implementation of GMDN recognizes only ‘active’ GMDN terms.
- Submit only active GMDN terms to the GUDID.

During submission of DI records:

- For DI record entry via the web user interface, the GMDN PT Code should be used to assign the GMDN term to the record; the Name and Definitions fields would be auto-populated. (For submission of GMDN terms in HL7 SPL xml files, see GUDID HL7 SPL Implementation Specification files, available at www.fda.gov/udi)

Maintaining GMDN Codes in DI Records:

- It is the responsibility of labelers to make sure their DI record information is accurate and up-to-date. If you maintain a membership with GMDN, the Agency notifies you when your terms have been modified or made obsolete. If not, it would be your responsibility to update your GMDN terms periodically or when required to by validation rules (see next bullet).
- If a GMDN term becomes obsolete, the labeler/LDE should update the GMDN term in order to pass validation when updating any other DI record attribute. An obsolete GMDN term doesn’t require an

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update, in and of itself, but when editing other attributes the DI record would not pass validation/review without an active GMDN term.

- Once a DI record has been published in the GUDID with an active GMDN term, that assignment remains until deliberately changed by the labeler/LDE. There is no automatic update of GMDN terms within the GUDID.
- If GMDN information changes, the updated information must be submitted within 10 business days of the change per 21 CFR 830.330(b).

GUDID GMDN Search Module

As stipulated in the Final UDI Rule [78 FR 58786], FDA has developed a GUDID search module, “Find FDA PT Codes” that enables users to select a GMDN term to be used in their GUDID submission until a GMDN Code can be obtained from the GMDN Agency. The FDA Preferred Term (PT) Codes are a 4-letter code assigned to each GMDN term, in place of the GMDN Code. The FDA PT Code is accepted into the GMDN Code attribute field in the DI Record and the GMDN Name and Definitions are auto-populated, as from GMDN Codes. The data entry requirement is met by entering a GMDN Code (5-digit) or FDA PT Code (4-letter); there is no need to enter both. Please do not attempt to enter a GMDN Code and an FDA PT Code for the same GMDN term. Since the FDA PT Codes only apply to GUDID DI Record entry and cannot be used in place of GMDN Codes for any other system, we encourage GUDID submitters to obtain the GMDN code and replace the FDA PT code as soon as possible. FDA PT Codes are also accepted in HL7 SPL xml document submission, but the same limitations apply. (For more details on GMDN entry in HL7 SPL xml files, see GUDID Draft HL7 SPL Implementation Specification, v1.1 at www.fda.gov/udi)

The Find FDA PT Code module can be found on the GUDID homepage after logging-in with a username and password. The Find module is separate from the DI record data entry module. There is no access to the ‘Find FDA PT Codes’ module from within a DI record. An LDE User should first search and select a GMDN PT Name (and associated FDA PT Code) for a specific device; then enter a DI record and use the FDA PT Code to assign the GMDN Name and Definitions to the DI record.

Labelers in need of assistance with term selection or new term development are encouraged to contact the GMDN Agency, www.gmdnagency.com.

NOTE: Representation of GMDN in *Appendix D*, Figure D1, a Fictitious Medical Device Label is for illustration purposes ONLY. GMDN PT Name and Definition are NOT expected to appear on the label of a device.

3.1.3 DI Record Life-Cycle

The GUDID DI Record Life-Cycle comprises the various states of a DI record and the associated business rules and functionality available to a user. Please note that the DI record life-cycle applies to both GUDID submission options – Web Interface and HL7 SPL xml file submission; where there are differences due to the type of submission, they have been noted.

3.1.3.1 DI Record States

A DI record is in one of three DI record states at any given time. The DI record state determines the applicable business rules and the GUDID functionality available to users.

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A new DI record may be saved in one of the following three DI record states: Draft DI record, Unpublished DI record, or Published DI record. Only DI records in a published state will be considered to have met the GUDID submission requirements under 21 CFR 830 Subpart E.

Draft DI Record: enables you to prepopulate and save a DI record with the available information via the GUDID Web Interface. Additionally, users may also create Draft DI records to get familiar with creating and saving DI records in GUDID; however, please do not *Submit* records for publishing when created solely for the purpose of familiarizing yourself with the system. Merely creating and saving Draft DI records does not fulfill your GUDID submission requirements under 21 CFR 830, subpart E. Please note that the Draft DI record state is only applicable to the GUDID Web Interface option. HL7 SPL submissions **cannot** be submitted as Draft DI records.

A Draft DI record:

- does not have to pass any business rules prior to being saved as a Draft DI record.
- can be edited an unlimited number of times via the GUDID Web Interface.
- can be saved in the Draft DI record state for 180 calendar days; the record will be “purged”, i.e., permanently removed from the GUDID, after 180 calendar days of inactivity.
 - Please note that the 180-day cycle resets and starts over each time the Draft DI record is edited and re-saved as a draft.
- can only be viewed/edited by the LDE user who created the record.
- is not available for public search and retrieval.

A Draft DI record must pass *Review*, i.e., pass business rules before it can be *Submitted* to GUDID. Upon submission, the record then can be in Unpublished or Published state based on the *Publish Date*:

- Unpublished state means *Publish Date* > today (i.e., a date in the future).
- Published state means *Publish Date* ≤ today (i.e., today or a date in the past).

Unpublished DI Record: enables users to complete a DI record and *Submit* it to GUDID prior to the required date. Saving unpublished DI records alone does not fulfill your GUDID submission requirements under 21 CFR 830, subpart E.

An Unpublished DI record:

- has passed all business rules, i.e., has passed *Review*.
- has not reached the *Publish Date* (*Publish Date* > today (i.e., a date in the future)).
- can be edited unlimited number of times; however, each time the record is edited, the record must pass business rules, i.e., *Review* again.
- can be copied to create new DI records, enabling reduction of data entry time; all attributes except for the Primary DI number and package information are copied.
- can be viewed by the FDA and LDE users assigned to the Labeler DUNS associated to the given DI record. FDA may review your Unpublished DI records for data quality assessment and contact you with questions.
- is not available for public search and retrieval.
- will be checked by an automated GUDID nightly process, and when *Publish Date* = today, the record will move to the Published DI record state.

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Published DI Record: a DI record that is available for search and retrieval by the public. We will consider you to have complied with the requirements of 21 CFR 830.330 on the date that the DI record is saved in GUDID in the published state.

A Published DI record:

- has passed all business rules, i.e., has passed *Review*.
- has *Publish Date* =<today (i.e., today or a date in the past). Please note that a DI record entered with *Publish Date* = today, will be available for public search immediately.
- can be copied to create new DI records, enabling reduction of data entry time; all attributes except for the Primary DI number and package information are copied.
- is available for public search and retrieval.
- is subject to editing limitations as determined by the **Grace Period**. The Grace Period is 7 calendar days and starts the day after the DI record is published.

Publish Date	Grace Period Start Date	Grace Period End Date
Monday, July 15, 2013	Tuesday, July 16, 2013	Monday, July 22, 2013, 11:59 PM

- Editing within-the-Grace-Period
 - all attributes, except *Publish Date* can be edited.
- Editing after-the-Grace-Period will be limited
 - New DI trigger attributes cannot be edited; these are core attributes which, when changed, no longer represent the same device and require a new DI.
 - certain attributes would have limited editing capability; a complete list of edit rules are available in the Data Elements Reference Table, available on www.fda.gov/udi . For example:
 - FDA Premarket Submission Number:
 - can 'Add' Premarket Submission Numbers after the grace period
 - cannot 'Edit' or 'Delete' existing values after the grace period
 - in the rare situation where New DI trigger attributes or attributes with limited editing need to be edited after-the-grace-period¹⁸, you may contact the [FDA UDI Help Desk](#) and request assistance.
 - FDA Staff will review your request and move your record to the Unpublished DI record state
 - You may make the necessary edits and submit the DI record again to be published.

Please note that Published DI records for devices removed from commercial distribution will remain in the published state and will be available for public search and retrieval. It is the responsibility of the labeler to update the DI records for discontinued devices. The *Commercial Distribution Status* will be auto-populated by the system based on *Commercial Distribution End Date* as shown below.

- When *Commercial Distribution End Date*> today (i.e., a date in the future) or null, *Commercial Distribution Status* = "In Commercial Distribution"
- When *Commercial Distribution End Date* =<today (i.e., today or a date in the past) , *Commercial Distribution Status* = "Not In Commercial Distribution"

¹⁸ Edits to New DI trigger attributes and attributes with limited editing after-the-grace-period is expected to be an extremely rare occurrence. Labelers should ensure their DI record data is accurate before the record moves to the published state.

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The table below provides a summary of the three DI record states:

DI Record State	Description	System Save duration	Possible Actions on the DI Record	Available via Public Search?
Draft DI record	Saved DI record that has not passed business rules <i>Please note that HL SPL Submissions cannot be submitted as Draft DI records. This state is only applicable to the GUDID Web Interface option.</i>	Purged after 180 calendar days of inactivity; if edited and resaved as draft, the 180-calendar day cycle resets and starts over	--Unlimited editing --Resave as Draft --Delete Draft --Must pass business rules and be <i>Submitted</i> to move to other DI record states	--No --only available to the LDE user who created the record
Unpublished DI record	DI record that has passed GUDID business rules, been <i>Submitted</i> to GUDID AND Publish Date > today (i.e., in the future)	Saved indefinitely	-- Copy --Unlimited editing --System publishes DI record when Publish Date = today	--No -- available for editing by LDE users assigned to the particular Labeler DUNS number --can be viewed by FDA
Published DI record	DI record that has passed GUDID business rules, been <i>Submitted</i> to GUDID AND Publish Date <= today (i.e., today or in the past) --Cannot move to other DI states without FDA staff intervention	Saved indefinitely	--Copy --Limited editing during and after Grace Period based on business rules	--Yes -- available for editing by LDE users assigned to the particular Labeler DUNS number --can be viewed by Coordinators, LDE users, FDA, Public Users

Table 1: Summary of DI Record States

3.2 GUDID Modules

Now that the key GUDID concepts are familiar, this section provides a description of the GUDID Modules.

The GUDID provides two options for submission of device identification information:

- 1) Submission of one DI record at a time via the secure GUDID Web Interface.
- 2) Submission of one DI record per XML file via the HL7 SPL submission option.

Both submission options require a GUDID account. Please note that the GUDID account is not by submission type, i.e., a labeler does not need to have a separate GUDID account for each submission option. The GUDID account identifies the labeler in GUDID and enables submission of device information via both options.

The overall concepts presented in this guidance document apply to both submission options. Where there are differences, they have been noted.

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GUDID provides two information retrieval options for published DI information:

- 1) Search and retrieval of device information via the web interface
- 2) Download and web service capabilities are planned for the future

GUDID accounts are NOT required for search and retrieval of published information.

During the initial implementation, GUDID Public Search will be temporarily disabled until a meaningful dataset of DI records have been created.

Figure 3 provides a pictorial representation of the GUDID modules described above.

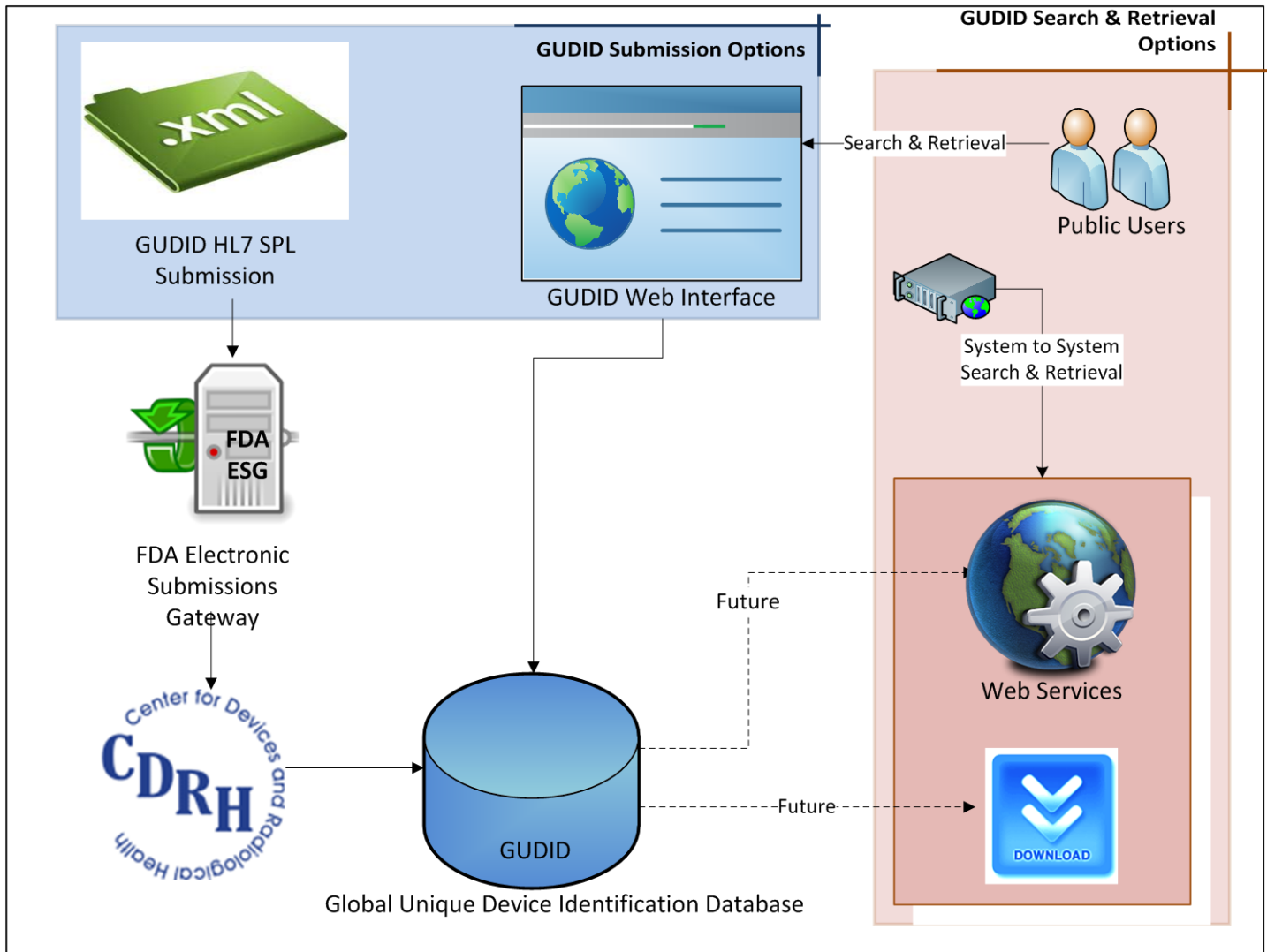


Figure 3: GUDID Overview

3.2.1 GUDID Web Interface

The GUDID Web Interface module enables creation of GUDID accounts, submission of DI records, and search and retrieval of device information. For details related to account creation, see section 3.1.1. This section focuses on submission of device information; search and retrieval details are presented in Section 3.2.3.

3.2.1.1 GUDID Device Identifier Module

The Device Identifier (DI) module enables creation and management of DI records by LDE users. As indicated in Section 3.1.1.2, when coordinators create LDE users, LDE users will receive a temporary login and password via a system generated email. LDE users may then login and use the GUDID.

The DI module enables LDE users to:

- Create DI records.
- Save, edit, and manage Draft DI records.
- Review and validate DI records against system business rules.
- Copy Unpublished and Published DI records.
- Edit and manage Unpublished and Published DI records.
- Search and retrieve ALL attributes of DI records for their assigned Labeler DUNS numbers. Note that this is different from public search users who can only view attributes indicated “public” in the Data Elements Reference Table, available on www.fda.gov/udi.

The next few sections detail the DI record life-cycle functions in GUDID¹⁹. These include:

- Creating a New DI Record
- Editing a Draft DI Record
- Editing Unpublished or Published DI Records
- Copying DI Records

3.2.1.1.1 Creation of a New DI Record

When created using the GUDID Web Interface, the DI record life-cycle begins with the creation of a new DI record, see Figure 4. Draft DI records **cannot** be submitted via the HL7 SPL submission option. Once created, a new DI record may be saved as a Draft DI record and *Reviewed* against the business rules. Based on the *Publish Date*, the record would then be promoted to the Unpublished or Published DI record state.

Figure 4 provides a pictorial representation of the new DI record creation process which is explained below.

¹⁹ For detailed information on the accessing and creating DI records in GUDID, please refer to the Global Unique Device Identification Database (GUDID) User Manual, available at --
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396841.pdf>

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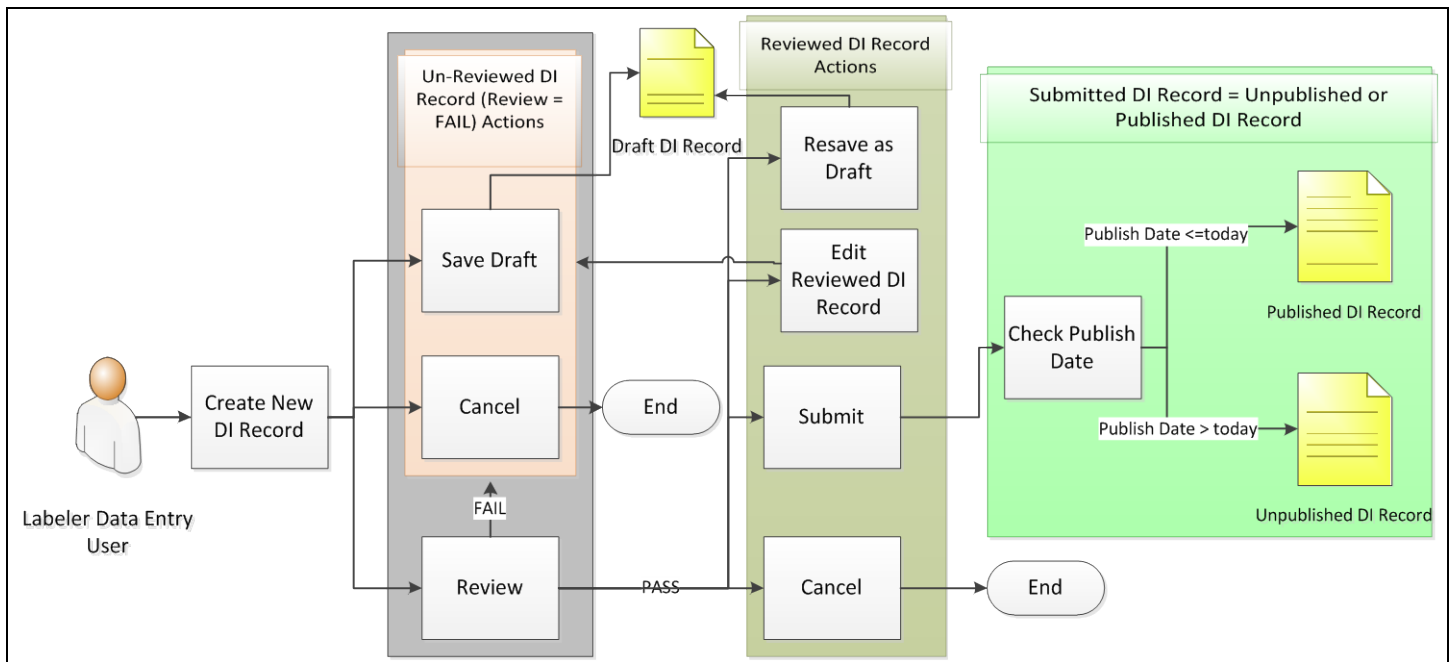


Figure 4: Creating a New DI Record

After creating a new DI record, the LDE user may choose to:

- *Save* the record as Draft DI record.
- *Cancel* creation of a new DI record.
- *Review* DI record to run GUDID business rules
 - If the record **FAILS** business rules, the user can:
 - *Save as Draft* DI record so errors can be fixed at a later time.
 - *Cancel* creation of new DI record.
 - If the record **PASSES** business rules, the user can:
 - *Resave as Draft* DI record.
 - *Edit* record further; once edited, the record must pass business rules again; it can be saved as Draft DI record, or edits can be *Cancelled*.
 - *Cancel* creation of new DI record.
 - *Submit* the record to GUDID; the DI record state will be set by the system based on *Publish Date*.
 - Unpublished state means *Publish Date* > today (i.e., a date in the future).
 - Published state means *Publish Date* <= today (i.e., today or a date in the past).

Note that *Submitting* a DI record to GUDID does not fulfill your GUDID submission requirements. We will consider you to have complied with the requirements of 21 CFR 830.330 on the date the DI record is saved in the published state.

3.2.1.1.2 Editing a Draft DI Record

As noted above, a new DI record created via the GUDID Web Interface can be saved as Draft DI record²⁰, which can move to other DI record states after it passes business rules. Draft DI records can be edited and resaved as Draft DI records.

²⁰ Draft DI records **cannot** be submitted via the HL7 SPL submission option.

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Figure 5 provides a pictorial representation of editing a Draft DI record, which is explained below.

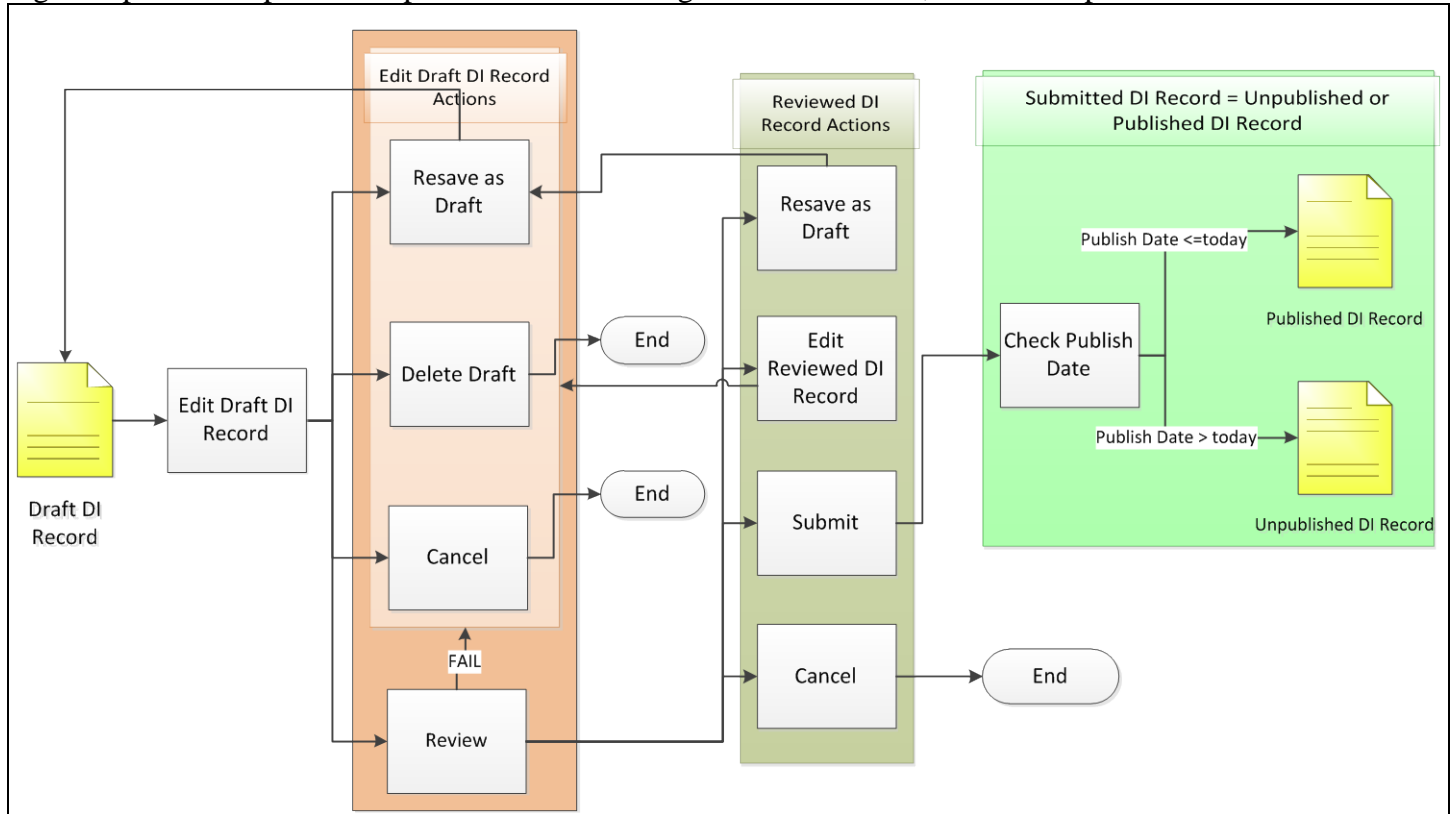


Figure 5: Editing a Draft DI Record

The LDE user can edit the Draft DI record and:

- *Save as Draft* again. Recall that Draft DI records can be edited and resaved as drafts an unlimited number of times.
 - A Draft DI record is purged from the system, i.e., permanently removed from GUDID, after 180 days of inactivity.
 - Each time a Draft DI record is edited, the 180 calendar day clock is reset as shown in the table below.
- *Delete* the Draft DI record.
- *Cancel* the edits.
- *Review* the Draft DI record to run GUDID business rules. See section 3.2.1.1.1, Creation of New DI Record, for details of the *Review* process.

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Table 2 below provides an example of how the purge date is reset.

Primary DI Number	User Action Date	User Action	Draft DI Record Edit Date	Purge Date	Comments
100	December 7, 2012	Enter and save a DI record as a draft via the GUDID Web Interface	December 7, 2012	June 5, 2013	Draft DI records are saved in the system for 180 calendar days after which the record is purged
100	December 17, 2012	Edit record, resave as draft via the GUDID Web Interface	December 17, 2012	June 15, 2013	Purge date is reset each time the record is edited and saved

Table 2: Draft DI Purge Date Examples

3.2.1.1.3 Editing Published or Unpublished DI Records

A DI record that has passed all business rules, i.e., is *Reviewed* and *Submitted*, automatically moves to either the Published or Unpublished DI record state based on the *Publish Date*, as explained earlier.

Published and Unpublished DI records can be edited as follows:

- Unpublished DI records can be edited an unlimited number of times and all attributes may be edited; however, once edited, the record must go through *Review* and pass business rules again.
- The extent of editing on a Published DI record is determined by the **Grace Period**, which starts the day after the DI record is published and ends after 7 calendar days. As explained earlier in the document:
 - within- the-grace period, all attributes, except *Publish Date* can be edited.
 - after-the-grace-period, editing will be limited.
 - New DI trigger attributes cannot be edited; these are attributes, which when changed, no longer represent the same device and would require a new DI.
 - Certain attributes will have limited editing capability.
 - See the GUDID Data Elements Reference Table, available on www.fda.gov/udi , for edit rules for all attributes.

Table 3 below illustrates the Grace Period concept via an example.

Primary DI Number	User/System Action Date	User/System Action	Publish Date	Grace Period Start Date	Grace Period End Date	Comments
100	July 19, 2013	Create a new DI record, pass business rules; save.	July 29, 2013	N/A	N/A	Unpublished record, grace period does not begin until the record is published

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Primary DI Number	User/System Action Date	User/System Action	Publish Date	Grace Period Start Date	Grace Period End Date	Comments
100	July 23, 2013	Edit record, change publish date	July 25, 2013	N/A	N/A	Unpublished record, grace period does not begin until the record is published
100	July 24, 2013	GUDID nightly system process publishes the record	July 25, 2013	July 26, 2013	August 1, 2013, 11:59PM	
100	July 27, 2013	Edit New DI trigger attribute within grace period, check that device is combination product	July 25, 2013	July 26, 2013	August 1, 2013, 11:59PM	Once published, grace period does not reset
100	August 2, 2013	Attempts to edit a New DI trigger attribute, Version or Model Number, but can not	July 25, 2013	July 26, 2013	August 1, 2013, 11:59PM	New DI trigger attributes CANNOT be edited after grace period ends

Table 3: Grace Period Example

In addition to editing Draft DI records as explained in Section 3.2.1.1.2, the LDE user can edit Unpublished or Published DI records and:

- *Review* the edited DI record to run GUDID business rules. See Section 3.2.1.1.1 above on Creation of a New DI Record for details of the *Review* process.
- *Cancel* the edits.

Figure 6 provides a pictorial representation of editing an Unpublished or a Published DI record.

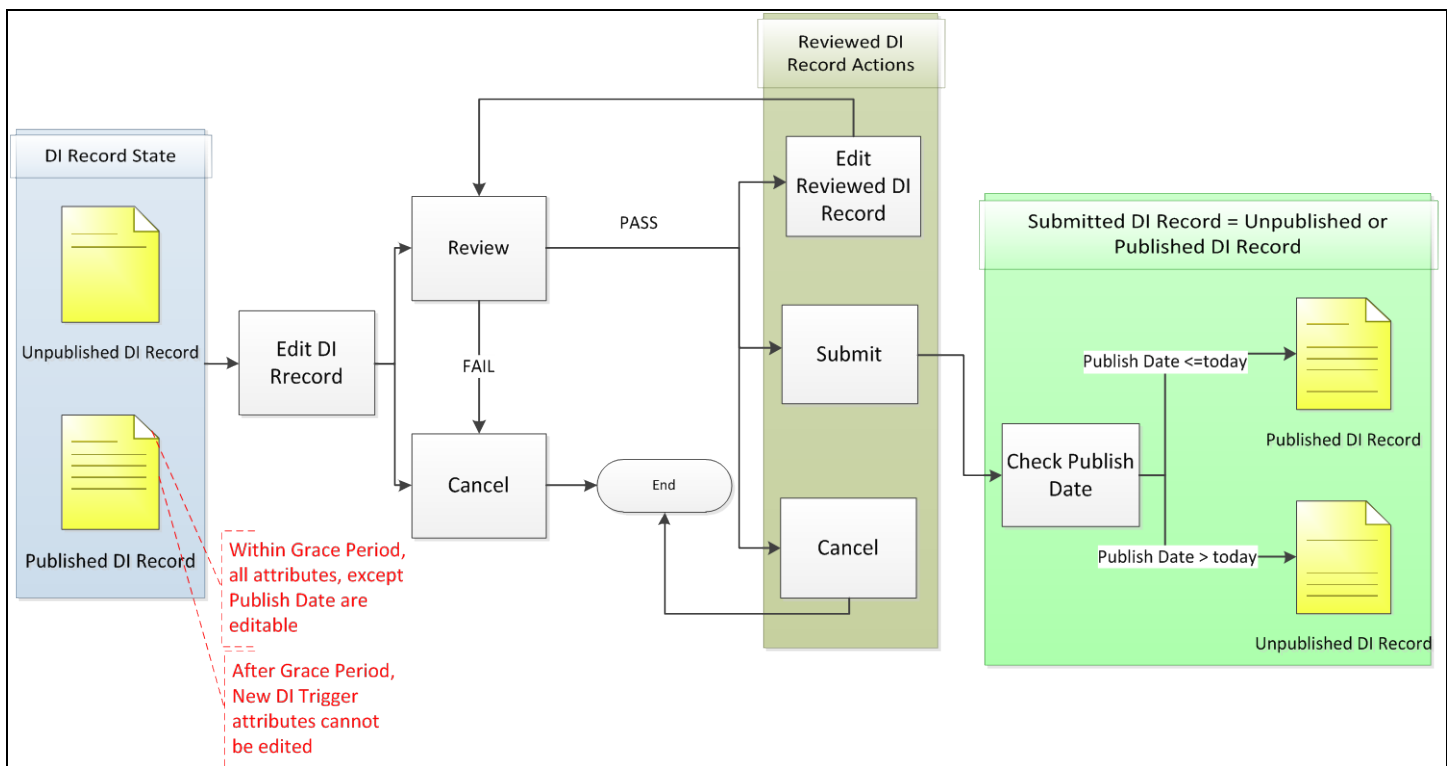


Figure 6: Editing an Unpublished or a Published DI Record

There is a key difference between editing a Draft DI record and editing an Unpublished or a Published DI record:

- after editing a Draft DI record, it can be resaved as a Draft DI record.
- after editing an Unpublished or a Published DI record, the record CANNOT be saved as a Draft DI record; the record has to pass business rules. The record must be *Reviewed* and *Submitted* or the edits will be cancelled.

All edits to Unpublished and Published DI records are logged in GUDID. LDE users may view the following information about the history of a DI record via the GUDID Web Interface – Edit Date, Edit Time and Name of the user who edited the DI record; for submissions edited via the HL7 SPL submission option, user is noted as “SPL User”. Details of which attributes were edited are presently not exposed and therefore not viewable by users. DI record history information is not exposed to public users of GUDID when a record is retrieved via GUDID Public Search.

GUDID offers two DI record submission options, the GUDID Web Interface and the HL7 SPL submission option. Entering a record via one option and editing via another option allows for the possibility of inconsistencies between the labeler’s source data and GUDID data. Therefore, for all edits to a DI record, we recommend you use the same submission option you used to initially create and submit the DI record to GUDID. The labeler is responsible for developing and maintaining SOPs for data quality and data integrity with respect to GUDID submissions.

3.2.1.1.4 Copying DI Records

Unpublished and Published DI records can be copied while using the GUDID Web Interface, however Draft DI records cannot.

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- The GUDID Web Interface DI record “Copy” function enables the user to copy all attributes of a DI record to a new DI record, except for the Primary DI number²¹ and package information. This enables the user to reduce data entry time.
- A copied record begins as a Draft DI record and must pass business rules to be promoted to other DI record states.

Figure 7 provides a pictorial representation of the *Copy* functionality in GUDID as explained below.

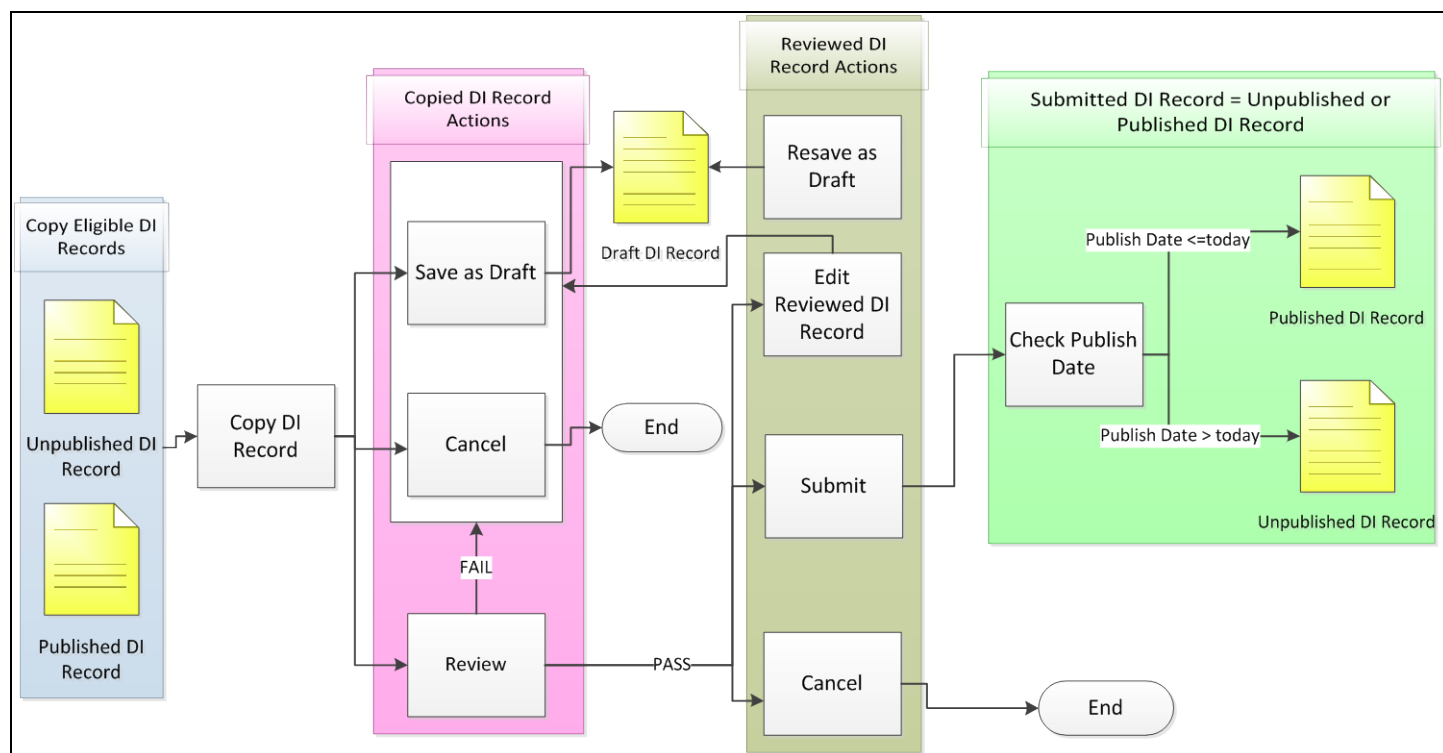


Figure 7: Copying DI Records

The LDE user can *Copy* Unpublished and Published DI records and:

- *Save as a Draft DI record.* Recall that the copied DI record begins as a Draft DI record and follows the DI record life-cycle to move to other DI record states.
- *Cancel* the copy action; the new DI record would not be saved in GUDID.
- *Review* the Copied DI record against GUDID business rules. See Section 3.2.1.1.1 above on Creation of a New DI Record for details of the *Review* process.

3.2.2 HL7 SPL Submission

The HL7 SPL Submission option enables companies to electronically submit device information one DI record at a time as an HL7 SPL xml file via the FDA ESG. For detailed technical specifications on HL7 SPL submission option, please refer to the **GUDID HL7 SPL Implementation Files**, available at <http://www.fda.gov/udi>.

Companies that choose the HL7 SPL submission option would need to do the following:

- Establish a GUDID account. See Section 3.1.1 for details.

²¹ Primary DI Number is the Device Identifier on the base package of a medical device.

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- Coordinator and Labeler Data Entry user roles are optional for HL7 SPL submissions since submissions are sent as XML files. However, if labelers choose to have Coordinator and LDE users, they may do so.
- Use the FDA ESG to submit HL7 SPL files.
 - Complete ESG account establishment and testing process. Visit www.fda.gov/esg for more information.
- Once GUDID and ESG accounts are established, companies would be required to complete GUDID testing prior to production submissions. Detailed information on testing requirements/process is available as part of the GUDID HL7 SPL Implementation Files on <http://www.fda.gov/udi>
- Companies may choose to use third-party submitters to submit device information on their behalf. Please review Section 3.1.1 for more information on using a third-party to submit device information to GUDID.
 - We are enabling third-parties to test their GUDID HL7 SPL submission solution by providing them with test GUDID accounts. Labelers using third-parties who may have completed testing must still complete the test scenarios listed as part of the GUDID HL7 SPL Implementation Files prior to moving to production GUDID HL7 SPL submissions.

3.2.3 Search/Retrieval of Device Information

The GUDID Search and Retrieval module would enable public users, i.e., consumers, health-care providers, hospital systems, to access published GUDID data. Published data would include all DI record attributes with a few exceptions such as: Labeler DUNS Number, Company Physical Address, GMDN Preferred Term Code, FDA Listing Number, etc. Please see the GUDID Data Elements Reference Table, available on www.fda.gov/udi for a list of attributes that are not released to the public.

During the initial implementation, GUDID Public Search will be temporarily disabled until a meaningful dataset of DI records have been created.

As indicated earlier, there would be two Search and Retrieval options available in GUDID:

- Search and retrieval of device information via the Web Interface
- System to system search and retrieval

Please note that GUDID accounts are not necessary for search or retrieval of published information.

3.2.3.1 GUDID Web Interface Search and Retrieval

The GUDID Web Interface search and retrieval module would provide the ability to:

- Search published GUDID data
- View results
- Export results as xml files

Two search options are available via the GUDID Web Interface:

- Quick Search – allows search on the following attributes: Device Identifier, Company Name, Brand Name, GMDN Preferred Term Name and Model Number.
- Advanced Search – allows search on additional GUDID attributes.

3.2.3.2 GUDID System to System Search and Retrieval

We plan to make available all published GUDID data as download files. Additionally, we also plan to make available basic web service functionality. Additional information on both these capabilities will be provided on the UDI webpage when available.

4 GUDID Submissions and 21 CFR 11 Requirements

There are two requirements necessary for Part 11 applicability:

- 1) Records that are required to be maintained (under predicate rules) or submitted to FDA
- 2) Records that are kept in electronic format, as opposed to paper

Labelers should become familiar with all the requirements of 21 CFR 11 and the Guidance document (Part 11 Electronic Records; Electronic Signatures – Scope and Application, which can be found at: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf>) which further defines a narrowed scope and identifies the requirements for which compliance is most important while Part 11 is being re-examined. When reading the Guidance document, ‘predicate rule’ should be interpreted as 78 FR 58786 or the UDI Rule.

All submitters – must retain records in accordance with 21 CFR 830.360. If those records are kept electronically, part 11 applies. However, a record that is not itself submitted, but is used in generating a submission, is not a part 11 record. That is, a record developed to collect all the data elements required to be entered into a device record via the GUDID web user interface, is not subject to part 11 requirements.

SPL submitters – must retain records in accordance with 21 CFR 830.360 and all records submitted to FDA. The HL7 SPL solution must be compliant with the requirements of part 11. The GUDID SPL submission doesn’t require a signature; therefore, part 11 requirements specific to electronic signatures (21 CFR 11 Subpart C), do not apply. However, please don’t confuse an electronic signature with a digital certificate. A digital certificate serves to authenticate the sender and is required for all submissions to the FDA ESG, including GUDID.

Once an SPL submission is successfully delivered to the GUDID, labelers should be able to view and edit data elements via the web interface. This allows for the possibility of inconsistencies between the labeler’s source data submitted via SPL and GUDID data. Labelers should develop and adhere to SOPs for data governance to maintain the quality of their device data.

Third-party submitters/Solutions Providers – are not responsible to the FDA to meet regulatory requirements for UDI or part 11. It is the legal responsibility of the labeler (or data owner) to meet the records requirements for 21 CFR 830.360 and the requirements of 21 CFR 11. The contractual language between labeler and third-party submitter is not the purview of the FDA.

5 Conclusion

This document provides GUDID information based on the current implemented system version. Enhancements and upgrades to GUDID are anticipated and the FDA intends to periodically update this document to reflect system changes.

Appendix A – GUDID Package Information Examples²²

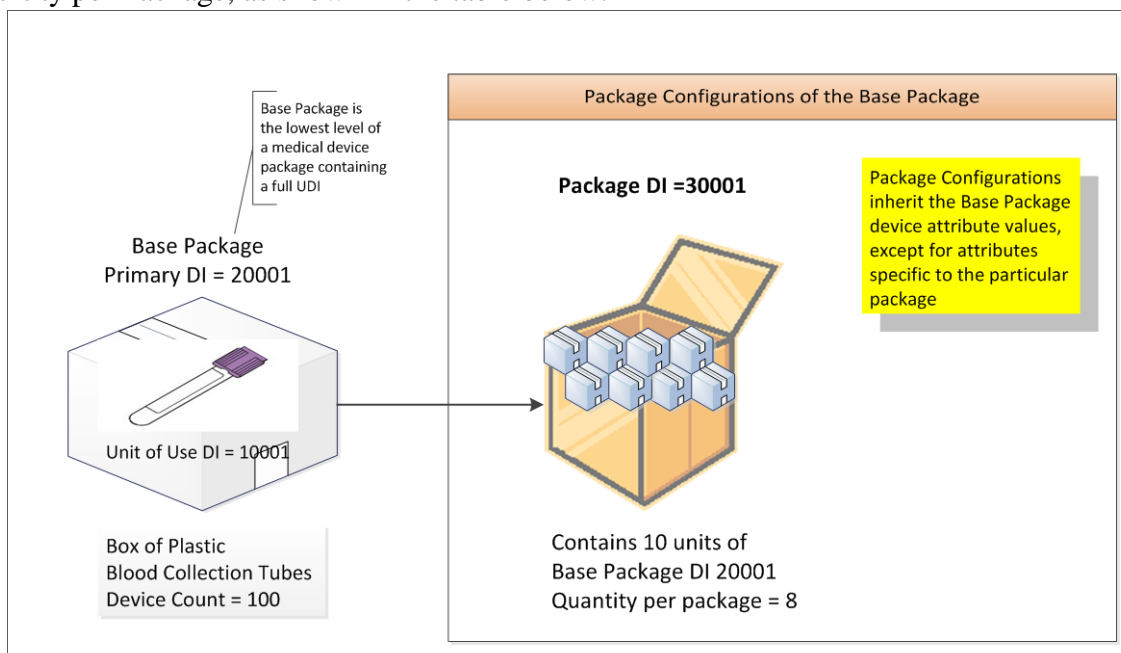
The examples below illustrate how package information is entered into the GUDID along with attribute values pertinent to packages.

EXAMPLE 1: UNIT OF USE DI + ONE PACKAGE LEVEL

The figure below provides a package configuration example for GUDID where the medical device has Unit of Use DI Number and one package level.

- Box of 100 single use blood collection tubes with the *Primary DI* 20001 and *Device Count* = 100.
 - Note that the tubes themselves do not have the DI on them as they fall under the general exception for individual single use device under 801.30(a)(3). Each tube however, gets a virtual *Unit of Use DI* assigned, and in this case, 10001.
- Case of 8 boxes (800 total), with *Package DI* 30001 (contains 8 of Primary DI 20001), *Quantity per Package* = 8.
- *Package Discontinue Date* is blank, therefore system auto-populates *Package Status* to “In Commercial Distribution.”

Package 30001 inherits all attribute values of base package 20001, except for the attributes specific to 30001 such as *Quantity per Package*, as shown in the table below.



Base Package

Primary Device Identifier	Device Count	Unit of Use DI
20001	100	10001

Package DI

Package DI	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status
30001	8	20001	Case		In Commercial Distribution

²² Device Identifiers used in all the examples are fictitious. Please refer to “UDI Formats by FDA Accredited Issuing Agency” (see Appendix C, available on www.fda.gov/udi) for correct format of the DI numbers by FDA Accredited Issuing Agencies.

Figure 1: GUDID Package Configuration Example 1

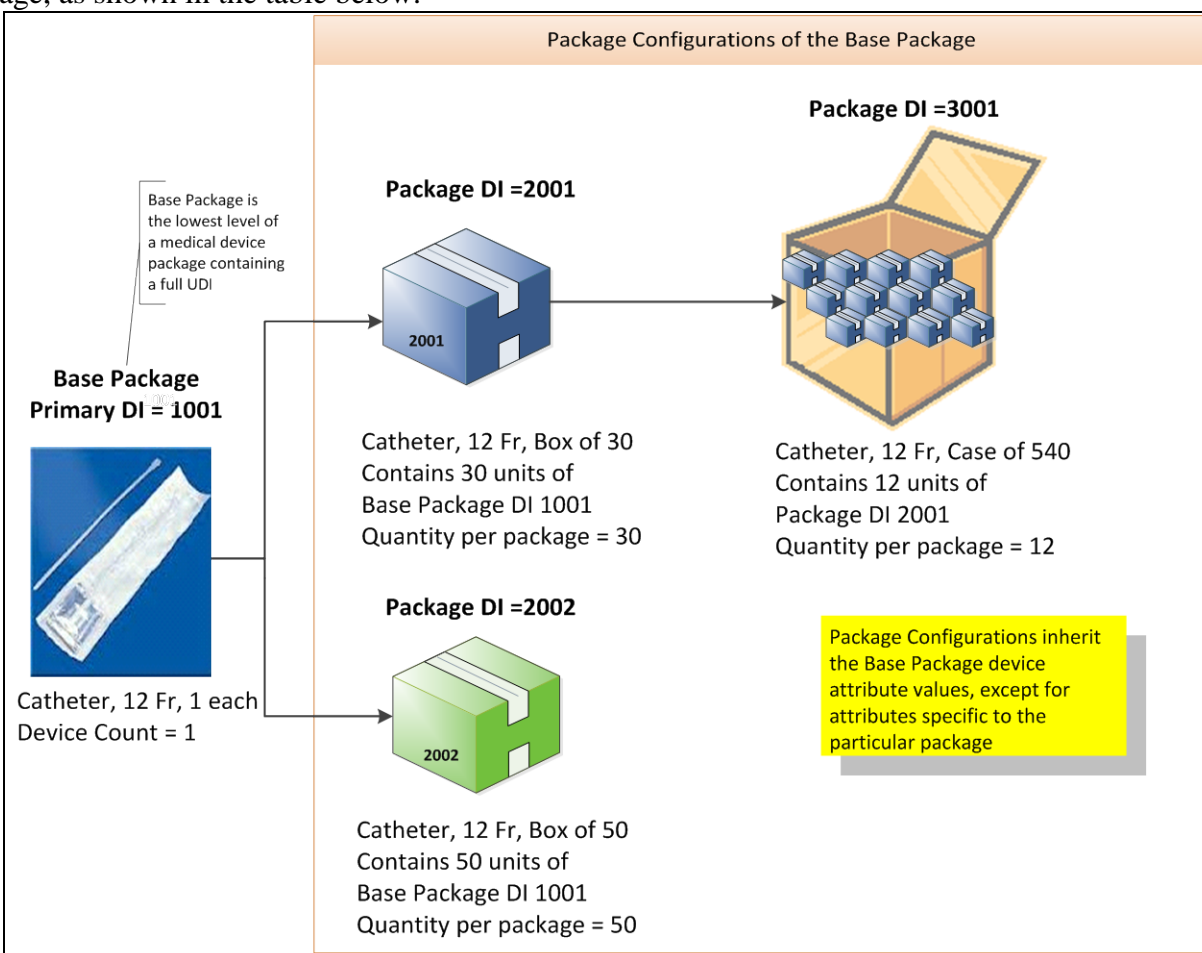
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EXAMPLE 2: DI ON INDIVIDUAL DEVICE + MULTIPLE PACKAGE LEVELS

The figure below provides a package configuration example for GUDID where the DI is on the individual device with two package levels.

- Catheter, 12 Fr, each with *Primary DI* 1001 and *Device Count* = 1.
- Box of 30 catheters with *Package DI* 2001 (contains 30 of *Primary DI* 1001).
- Case of 12 boxes (540 catheters), with *Package DI* 3001 (contains 12 of *Package DI* 2001).
- Box of 50 catheters with *Package DI* 2002 (contains 50 of *Primary DI* 1001).
- *Package Discontinue Date* is blank, therefore system auto-populates *Package Status* to “In Commercial Distribution.”

Package 2001, 3001 and 2002 inherit all attribute values of base package 1001, except for the attributes specific to each package, as shown in the table below.



Base Package

Primary Device Identifier	Device Count
1001	1

Package DI

Package DI	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status
2001	30	1001	Box		In Commercial Distribution
3001	12	2001	Case		In Commercial Distribution
2002	50	1001	Box		In Commercial Distribution

Figure 2: Package Configuration Example 2

Appendix B – GUDID Data Elements Reference Table

For a complete list of GUDID attributes, please refer to the GUDID Data Elements Reference Table available at www.fda.gov/udi

Appendix C – UDI Formats by FDA Accredited Issuing Agency

For information on UDI Formats by FDA Accredited Issuing Agency, please visit www.fda.gov/udi

The diagram shows a medical device label for "CompuHyper GlobalMed® Ultra Implantable™". The label includes the following information:

- Brand Name:** CompuHyper GlobalMed®
- GMDN Description:** Fictitious Medical Device
- Catalog Number:** CAT 123456
- Production Identifier: Lot Number:** LOT 12345678
- For Single Use:** SINGLE USE (indicated by a crossed-out person icon)
- USE BY:** 2020-01-01 (indicated by an hourglass icon)
- DO NOT USE IF PACKAGE IS DAMAGED** (indicated by a crossed-out box icon)
- QTY:** 1 EA
- Storage and Handling:** UPPER LIMIT OF TEMPERATURE 45°C (indicated by a thermometer icon) and KEEP DRY (indicated by an umbrella icon).
- Manufacturer:** CompuHyperGlobalMed, 123 Technology Dr, Somewhere, XX 00000. Contact info: 800.555.1234 (USA), 555.555.1234 (All Others), www.chgm.com.
- Labeler Name & Labeler Physical Address:** MedDevfront UK, Somewhereshire, XX12 3XX UK. Website: www.mdl.co.uk.
- Unique Device Identifier (DI & PI):** A barcode representing the unique identifier.

Figure D1: GUDID Attributes Mapped to a Fictitious Medical Device Label

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Abbreviations & Acronyms

Term	Description
DI	Device Identifier
D&B	Dun & Bradstreet
DUNS	Data Universal Numbering System
ESG	FDA Electronic Submissions Gateway
GMDN	Global Medical Device Nomenclature
GUDID	Global Unique Device Identification Database
HCT/P	Human Cell, Tissue or Cellular or Tissue-Based Product
FDA	Food and Drug Administration
FDAAA	FDA Amendments Act
FDASIA	FDA Safety and Innovation Act
HL7	Health Level 7
PI	Production Identifier
GMDN PT	GMDN Preferred Term
SPL	Structured Product Labeling
UDI	Unique Device Identifier

Glossary

Term	Description
Base Package	The lowest level of a medical device package containing a full UDI. The DI on the base package is the Primary DI.
Coordinator	Individual(s) responsible for management of the GUDID account, for designated Labelers.
Data Universal Numbering System (DUNS)	A unique 9-digit identification number assigned and managed by Dun & Bradstreet to business entities.
Device Identifier (DI)	A mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.
Device Identifier Record (DI Record)	The DI, together with associated data attributes constitutes a DI record for a particular device version or model.
DI Record Life-Cycle	Comprises of the various states of a DI record and the associated business rules and functionality available to a user.
DI Record States	A DI Record is in one of three DI Record States at any given time: Draft DI Record, Unpublished DI Record, or Published DI Record.
Direct Marking DI	An identifier that is marked directly on the device; can be the same as or different from the Primary DI; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.
Device Package	A package that contains a fixed quantity of a particular version or model of a device.
Draft DI Record	Saved DI record that has not passed business rules.
Electronic Submissions Gateway (ESG)	An FDA-wide solution for accepting secure electronic regulatory submissions.
FDA Preferred Term	The FDA Preferred Term (PT) Codes are a 4-letter code assigned to each GMDN term, in place of the GMDN Code. FDA PT Codes only apply to GUDID DI Record entry ONLY and cannot be used in place of GMDN Codes for any other system.
Global Medical Device Nomenclature (GMDN)	A system of internationally agreed descriptors used to identify medical device products and is managed by the GMDN Agency.
Grace Period	Seven calendar days and starts the day after the DI record is published; determines the extent of editing possible on a DI record.
GUDID	Global Unique Device Identification Database, the repository of device identification information for devices specified under the FDA UDI Final Rule.
GUDID Account	A GUDID account enables companies to access and submit information to the GUDID.

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Term	Description
GUDID Web Interface	An online interface that enables secure account creation, secure submission of DI records, and search and retrieval of device information.
Health Level 7 (HL7)	A standards development organization, whose mission is to provide messaging standards for interoperability, exchange, management, and integration of data that supports clinical patient care and the management, delivery, and evaluation of healthcare services.
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs.
Labeler	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.
Labeler Data Entry (LDE) User	Individual(s) responsible for day to day entry, submission and management of device identification information for designated Labeler DUNS into the GUDID.
Listing Number	Number assigned by FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f)
New DI Trigger Attributes	Attributes, which when changed, no longer represent the same device thereby requiring the creation of a new DI.
Package	According to 21 CFR 801.3, a package is defined as a fixed quantity of a particular version or model of a device.
Package DI	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers).
Primary DI	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The Primary DI would be located on the base package, which is the lowest level of a medical device containing a full UDI. For medical devices without packaging, the Primary DI number and full UDI may be on the device itself.
Product Code	Three letter classification code for pre-market devices issues by FDA.

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Term	Description
Production Identifier(s) (PI)	A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: (i) The lot or batch within which a device was manufactured; (ii) The serial number of a specific device; (3) The expiration date of a specific device; (iv) The date a specific device was manufactured. (v) For an HCT/P regulated as a device, the distinct identification code required by § 1271.290(c).
Published DI Record	A DI record that is published, and therefore is available for search and retrieval by the public.
Regulatory Contact	Individual responsible for management of GUDID submission requirements for the Labelers in a given GUDID account.
Relabler	Relabeler, for the purposes of 21 CFR 830.60, is a new labeler that changes the content of the labeling from that supplied from the original labeler for distribution under the new labeler's own name. A relabeler does not include labelers that do not change the original labeling but merely add their own name.
Secondary DI	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI.
Structured Product Labeling (SPL)	A HL7 standard for the exchange of product information using extensible markup language.
Support Contact	Contact for consumers and healthcare providers to obtain additional information about the device.
Third-party submitters	Companies/individuals (contractors, vendors) authorized to submit GUDID information on behalf of the Labeler.
Unique Device Identifier (UDI)	A unique numeric identifier composed of the device identifier and production identifier(s) that uniquely identify a medical device through distribution and use.
Unit of Use DI	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.
Unpublished DI Record	DI record that has passed GUDID business rules <i>AND</i> Publish Date > today.