

Global Unique Device Identification Database (GUDID)

Draft Guidance for Industry

DRAFT GUIDANCE

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**U.S. Department of Health and Human Services
Food and Drug Administration**

**Center for Devices and Radiological Health
Office of Surveillance and Biometrics
Informatics Staff**

Center for Biologics Evaluation and Research

Preface

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Global Unique Device Identification Database (GUDID)

Draft Guidance for Industry

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 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 who 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

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.”

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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, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe 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) will be created and maintained by device labelers based on global device identification standards managed by FDA-accredited Issuing Agencies². The standard formats for the three prospective issuing agencies are provided in *Appendix C*.

With certain exceptions, a UDI will be required to appear on the label of a medical device and be 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:
 - 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 1271.290(c).

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

The DI can be used to look up information about the device in the GUDID.

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 will contain only production identifier flags to indicate which PI attribute(s) are on the device label.

The data elements described in the UDI Final Rule are included in the GUDID. The GUDID also contains certain ancillary administrative data used to develop and maintain the GUDID, as well as to facilitate integration of DI information with other internal FDA systems. A complete list of GUDID attributes and descriptions are provided in *Appendix B*. It is important to note that a majority of the data attributes in the

² Refer to the UDI Final Rule (<http://www.fda.gov/udi>) for details on issuing agencies and their role in UDI assignment.

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GUDID appear on the medical device label. Data attribute values in the GUDID are intended to be consistent with their representation on the label. See example in *Appendix D*.

The design principles guiding GUDID development include the following:

- Standards-based submission with two options:
 - Structured input via the GUDID Web Interface
 - Health Level 7 (HL7)³ Structured Product Labeling (SPL)⁴ submission via the FDA Electronic Submissions Gateway (ESG)⁵.
- Standards-based data repository with controlled vocabularies including:
 - Dun & Bradstreet (D&B) Number (DUNS)⁶
 - Global Medical Device Nomenclature (GMDN)⁷
 - FDA Product Codes
- Free and public access to the device information in GUDID via public search and web service capability; 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. Following this section, details on each of the GUDID modules are presented.

3.1.1 GUDID Account

Labelers that are required to submit information to the GUDID must first request a GUDID account. The structure of the GUDID Account and relationship of user roles is depicted in Figure 1.

³ 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.

⁴ Structured Product Labeling (SPL) is a HL7 standard for the exchange of product information using extensible markup language (XML).

⁵ FDA ESG enables the secure submission of regulatory information. For more information, please visit: <http://www.fda.gov/esg>

⁶ 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>

⁷ 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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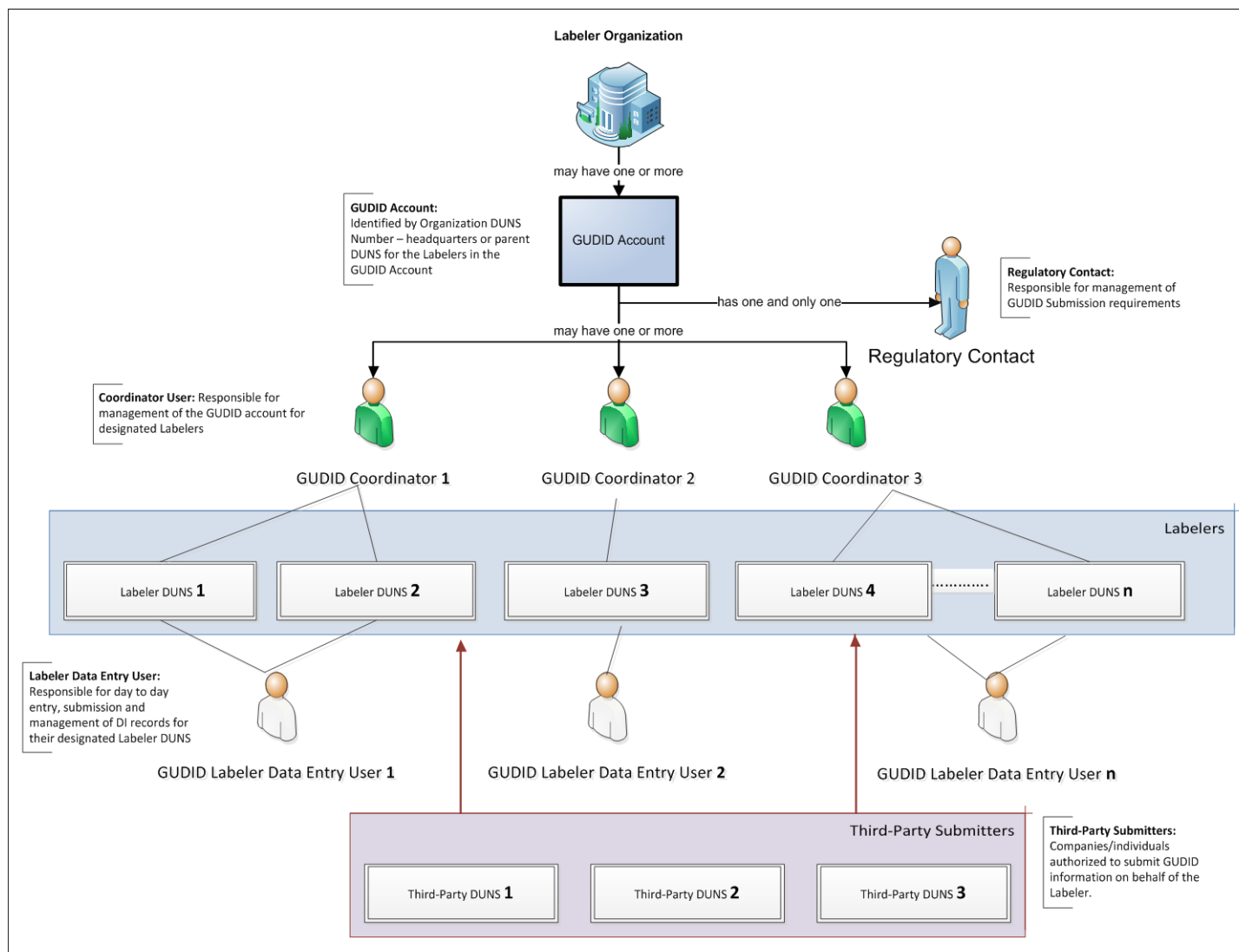


Figure 1: GUDID Account and User Roles

- A Labeler Organization may have one or more GUDID accounts.
- Each GUDID account is identified by a 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 the GUDID will obtain company name and address from the DUNS database.
- Each account will have only one Regulatory Contact. A regulatory contact:
 - Is the individual responsible for management of GUDID submission requirements for the Labelers in a given GUDID account.
 - Will be contacted by FDA on matters pertaining to GUDID regulatory submission requirements.
- Each GUDID account will have one or more Coordinators.
 - Each Coordinator will be assigned one or more labelers, identified by Labeler DUNS numbers, in a given GUDID account.
 - Coordinators manage the GUDID account for their designated Labelers. Responsibilities include:
 - Create Labeler Data Entry (LDE) User account(s) (see below);

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- Assign Labeler DUNS number(s) to LDE(s);
- Create LDE User role for a third-party (see below), if so desired;
- Serve as LDE user, if so desired.
- Each GUDID account will have one or more labelers.
 - Labelers will be identified by Labeler DUNS numbers; device information would be submitted for the Labelers identified in the GUDID account.
 - Please note that the labeler name and address retrieved from D&B database should match the name and address on the medical device label for which the device identification information is submitted to GUDID.
- Each GUDID account will have one or more LDE Users.
 - Each LDE user will be assigned one or more labelers, identified by Labeler DUNS numbers, in a given GUDID account.
 - Each LDE User will be responsible for data entry, submission, and management of device identification information for their designated Labeler DUNS into the GUDID.

The labeler has the option to designate third-party submitters for GUDID submissions. Third-party submitters are companies/individuals (contractors, vendors) authorized to submit GUDID information on behalf of the labeler.

- Each GUDID account may have zero or more third-party submitters.
 - In order to enable third parties to submit to GUDID, the following should be noted:
 - Companies should identify the third-party in their GUDID account by providing third-party DUNS number(s) to FDA during GUDID account request.
 - By identifying the third-party, the company is authorizing the third-party to submit GUDID information on their behalf.
 - GUDID HL7 SPL submissions by third parties not identified in a GUDID account will be rejected.
 - GUDID Coordinators may provide third parties with LDE user accounts, if so desired.

Note that GUDID account user contact information is used for internal FDA purposes only; this information is not made public.

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. A detailed description of the account establishment process is in section 3.2.1.1 of this document.

Search and retrieval of GUDID information, both via web interface and web service, does not require a GUDID account.

3.1.2 Device Identifier (DI) Record

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

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The DI, together with associated data attributes⁸, constitutes a DI Record in the GUDID which 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, and manufacturing date) appear on the label of the device.
- 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.
- 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 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 marked directly on the device; can be the same as or different from the Primary DI.
 - Package DI: A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers).
- All DIs will be checked for uniqueness in the GUDID. Once used, a DI can never be reused, even if the product is no longer in commercial distribution.
 - When *Commercial Distribution End Date* <= today, 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*”.
- 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.

Each DI record will be subject to GUDID business rules to ensure data quality. Business rules include the following:

- Required data attributes must be provided – see *Appendix B* for a list of required attributes.
- 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.
- 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 (See section 3.1.3.1).

3.1.2.1 Package Information in GUDID

A device package means a package that contains 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. 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)

⁸ See *Appendix B* for a list of data attributes

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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:

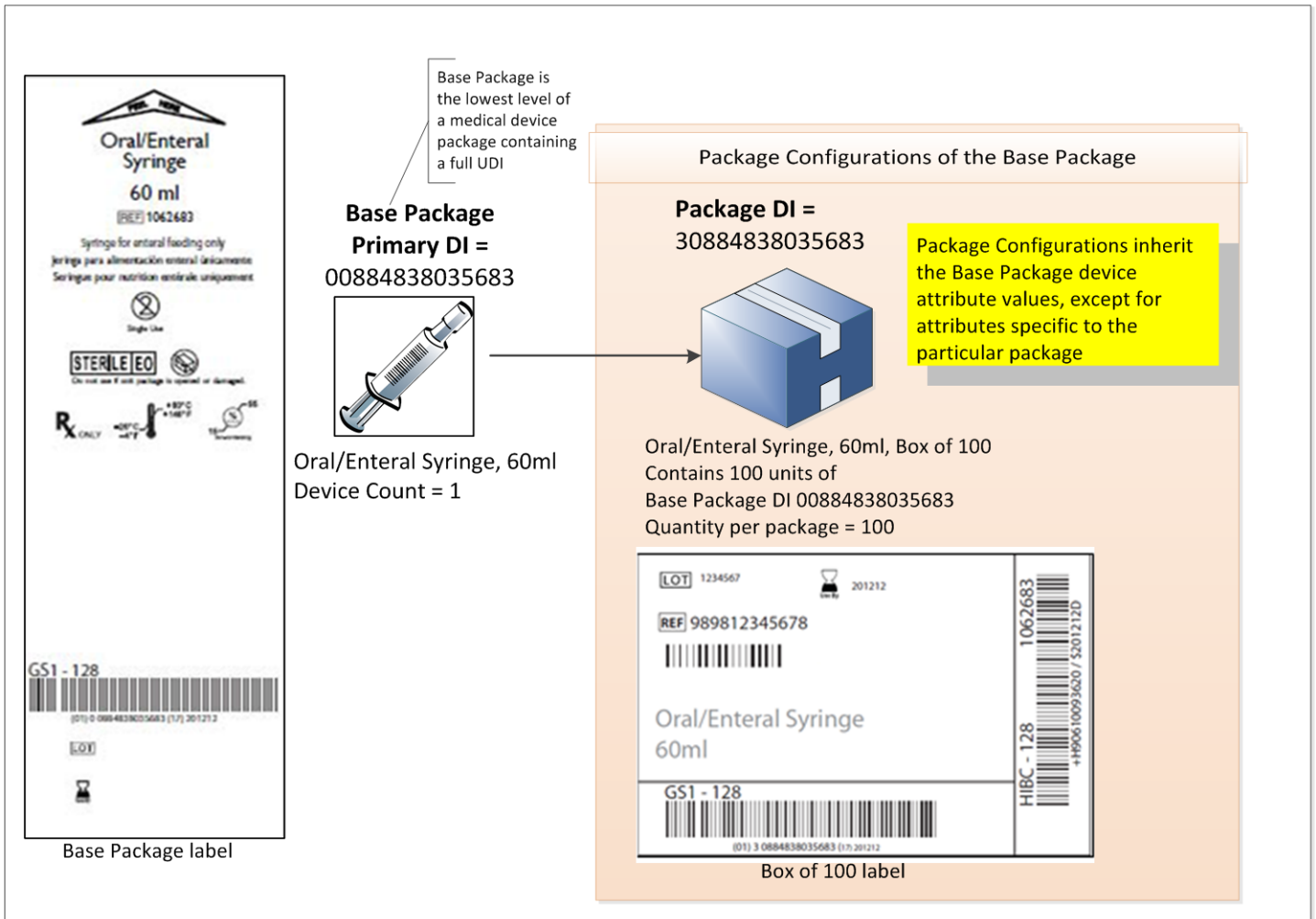
- The Primary DI number for a DI record identifies the lowest level of medical device package containing a full UDI; also known as the base package. The Primary DI, therefore, is also the base package DI.
- The Device Count attribute provides the number of medical devices in the base package.
- Package configurations of the base package are part of the base package DI record.
- Package configurations inherit base package attribute values, except for attributes specific to that particular package. Therefore, attribute information needs to be provided only once and applies to all packages. The attributes specific to a package include:
 - Package Device Identifier – DI for the particular package configuration.
 - 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 that describes the type of packaging of the product (box, carton, etc.) and assists users to understand the 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 available or discontinued; auto-populated by the system based on Package Discontinue Date:
 - *Package Discontinue Date*>today or null, *Package Status* = “In Commercial Distribution”
 - *Package Discontinue Date*=< today, *Package Status* = “Not In Commercial Distribution”

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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 30884838035683 (contains 100 units of Primary DI 00884838035683).
- *Package Discontinue Date* is blank; therefore *Package Status* is set to “In Commercial Distribution.”

Package 30884838035683 inherits all attribute values of base package 00884838035683, except for the attributes specific to 30884838035683, 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
30884838035683	100	00884838035683	Box		In Commercial Distribution

Figure 2: Package Configuration Example⁹

⁹ Label courtesy of GUDID External User Acceptance Testing participant

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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 will require entry of one or more GMDN Preferred Term (PT) codes.

GMDN is a system of internationally agreed descriptors used to identify medical device products and is managed by the GMDN Agency. GMDN has 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.

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 PT codes for submission to the GUDID, companies should first obtain a license. Visit <http://www.gmdnagency.com/default.aspx> for details.

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

- Identify and obtain appropriate GMDN codes for devices requiring GUDID submission.
 - Please note that development of new terms requires time, so please plan accordingly.
- If your company has PTs that are being used, determine if they are “active” or “obsolete” in the GMDN vocabulary.
- If the GMDN code is obsolete, identify “replacement” terms.
 - Please note that this process may take time, so please plan accordingly.
- Submit only active PTs to the GUDID.

FDA is working to develop a GUDID search tool that will enable users to select a GMDN term to be used in their GUDID submission until a GMDN code can be obtained from the GMDN Agency. This search tool will be made available in the near future.

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.

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.

Draft DI Record: enables users to create and save an incomplete DI record via the GUDID Web Interface. 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.

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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.
- can be saved in the Draft DI record state for 180 calendar days; if the record remains in the draft DI state after 180 calendar days, it will be “purged”, i.e., permanently removed from the GUDID.
 - 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 to be promoted to other DI record states as follows:

- Unpublished state means *Publish Date* > today.
- Published state means *Publish Date* =< today.

Unpublished DI Record: enables users to prepopulate data to complete a DI record prior to the GUDID submission date.

An Unpublished DI record:

- has passed all business rules.
- has not reached the *Publish Date* (*Publish Date* > today).
- can be copied to create new DI records, enabling reduction of data entry time; all attributes except for the Primary DI number can be copied.
- can be edited unlimited number of times; however, once edited, the record must pass business rules again.
- 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.

Published DI Record: a DI record that is available for search and retrieval by the public.

A Published DI record:

- has passed all business rules.
- is available for public search and retrieval.
- has *Publish Date* >=today. 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 would be copied.
- cannot move to any other DI record state without FDA staff intervention¹⁰.
- 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 During-the-Grace-Period
 - all attributes, except *Publish Date* can be edited
- Editing After-the-Grace-Period will be limited

¹⁰ Changing DI record states after a record is in the published state is expected to be an extremely rare occurrence and not routine practice. Users should ensure their data is accurate before their record moves to the published DI record state.

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- 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 *Appendix B*. 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

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. 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, *Commercial Distribution Status* = “Not In Commercial Distribution”
- When *Commercial Distribution End Date* > today or null, *Commercial Distribution Status* = “In Commercial Distribution”

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 from the date the record is saved; 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 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 AND Publish Date > today	Saved indefinitely	-- Copy --Unlimited editing --System publishes DI record when Publish Date = today	No; only available to LDE users assigned to the particular Labeler DUNS number.
Published DI record	DI record that has passed GUDID business rules AND Publish Date <= today --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

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.

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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; no batch submissions.

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.

GUDID will provide two information retrieval options for published DI information:

- 1) Search and retrieval of device information via the web interface
- 2) System to system search and retrieval via web service (download capability is 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.

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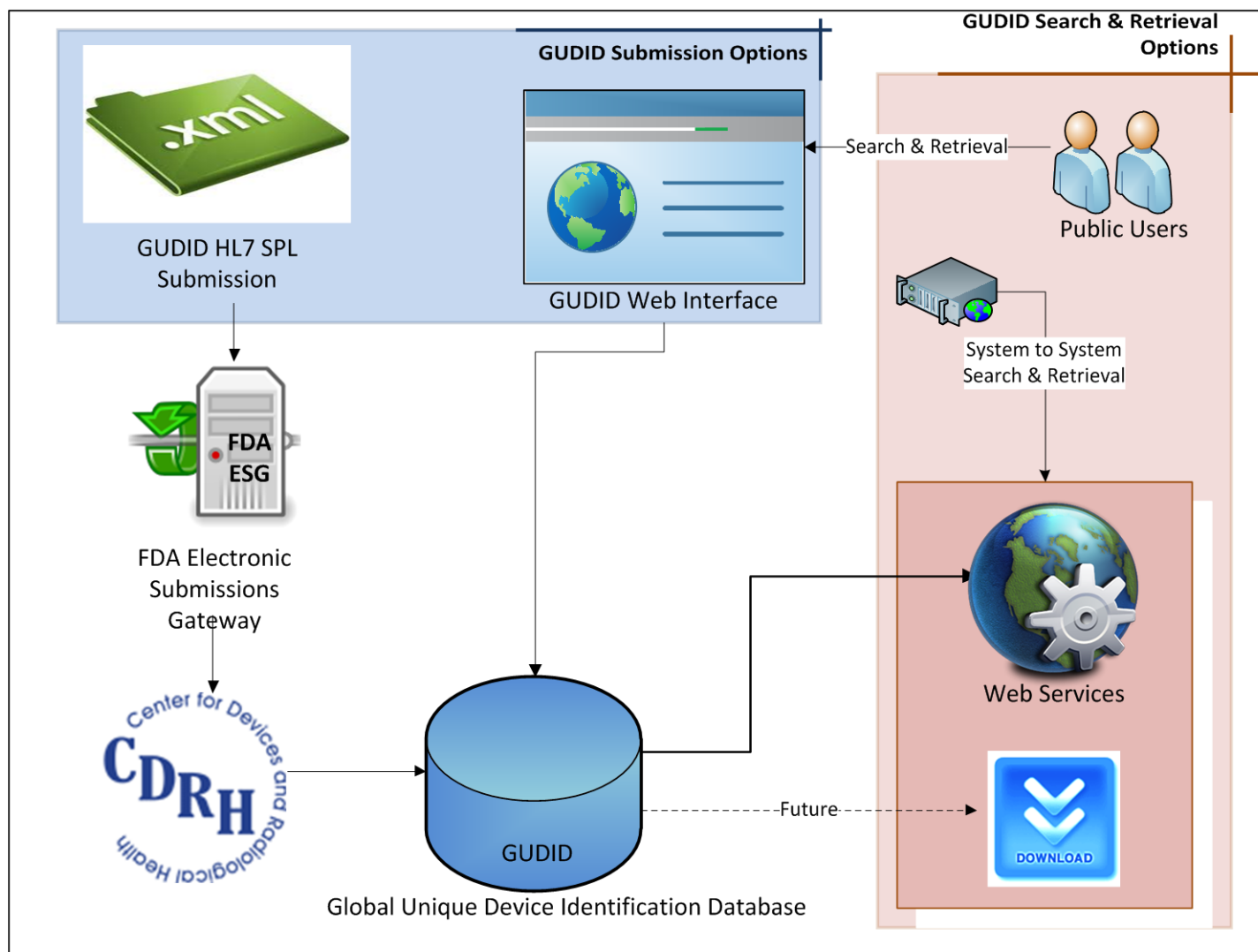


Figure 3: GUDID Overview

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. This section focuses on account creation and submission of device information; search and retrieval details are presented in Section 3.2.3.

3.2.1.1 GUDID ACCOUNT MANAGEMENT MODULE

The Account Management module enables creation and management of GUDID accounts by FDA staff. A GUDID account is required for submitters of device information, i.e., labelers, regardless of the submission option chosen, GUDID Web Interface or HL7 SPL xml file submission. Initially, a paper process will be used to create and manage accounts; an online process is envisioned for the future.

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3.2.1.1.1 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 Number(s) to be used to represent your GUDID account.
 - If your company does not have a DUNS number(s), 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 organization 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 accordingly before submitting to GUDID.
- Identify individuals for the various user roles in GUDID -- Regulatory Contact, Coordinator(s) and LDE user(s).
- 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.

3.2.1.1.2 GUDID ACCOUNT REQUEST PROCESS

Once the necessary information is gathered, a GUDID account request must be submitted to the FDA. Visit <http://www.fda.gov/udi> for information on how/where 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 will obtain company name and address from the DUNS database.
- Regulatory Contact information – name, email, phone, physical address.
- Labeler DUNS for the GUDID Account – please note that the Labeler name and address retrieved from the DUNS database should match the name and address on the medical device label (for which the device identification information will be submitted to GUDID)
 - Coordinator(s) 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

Note that GUDID account user contact information is used for internal FDA purposes only; this information is not made public.

Once FDA Staff receive the GUDID account request, the GUDID account will be created; Coordinator(s) will receive login information and a temporary password via a system generated email.

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Each GUDID account would have at the minimum:

- one Regulatory Contact
- one Labeler DUNS number
- one Coordinator

Once a GUDID account is created:

- Web Interface users may login and begin using GUDID.
 - Coordinator user(s) may access the system via their temporary login and password to create LDE Users
 - Coordinators require 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, LDE users will receive temporary login and password via system generated email.
- HL7 SPL submitters, please refer to section 3.2.2 below for additional details.

3.2.1.1.3 GUDID ACCOUNT CHANGES

To make changes to an existing GUDID account, please contact the FDA UDI help-desk. 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

It is recommended that labeler organizations identify an individual to manage GUDID account changes.

3.2.1.2 GUDID Device Identifier Module

The Device Identifier (DI) module enables creation and management of DI records by LDE users. As indicated in Section 3.2.1.1.2, when coordinators create LDE users, LDE users will receive temporary login and password via system generated email. LDE users may then login and use the GUDID.

The DI module enables LDEs 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 *Appendix B*.

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

- Creation of a New DI Record
- Editing a Draft DI Record

Contains Nonbinding Recommendations

- Editing Unpublished or Published DI Records
- Copying DI Records

3.2.1.2.1 CREATION OF A NEW DI RECORD

The DI record life-cycle begins with the creation of a new DI record, see Figure 4. Once initiated, 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.

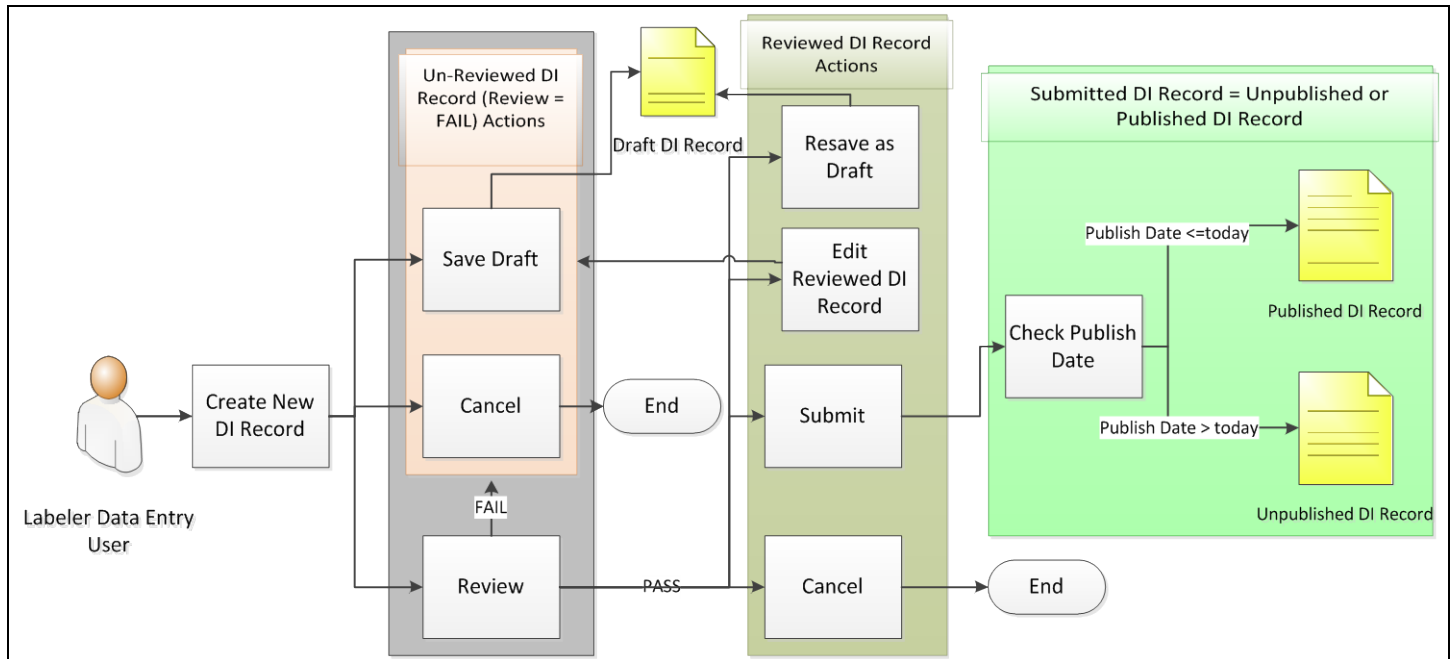


Figure 4: Creating a New DI Record

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.
 - Published state means *Publish Date* =< today.

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3.2.1.2.2 EDITING A DRAFT DI RECORD

As noted above, a new DI record can be saved as Draft DI record, 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.

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

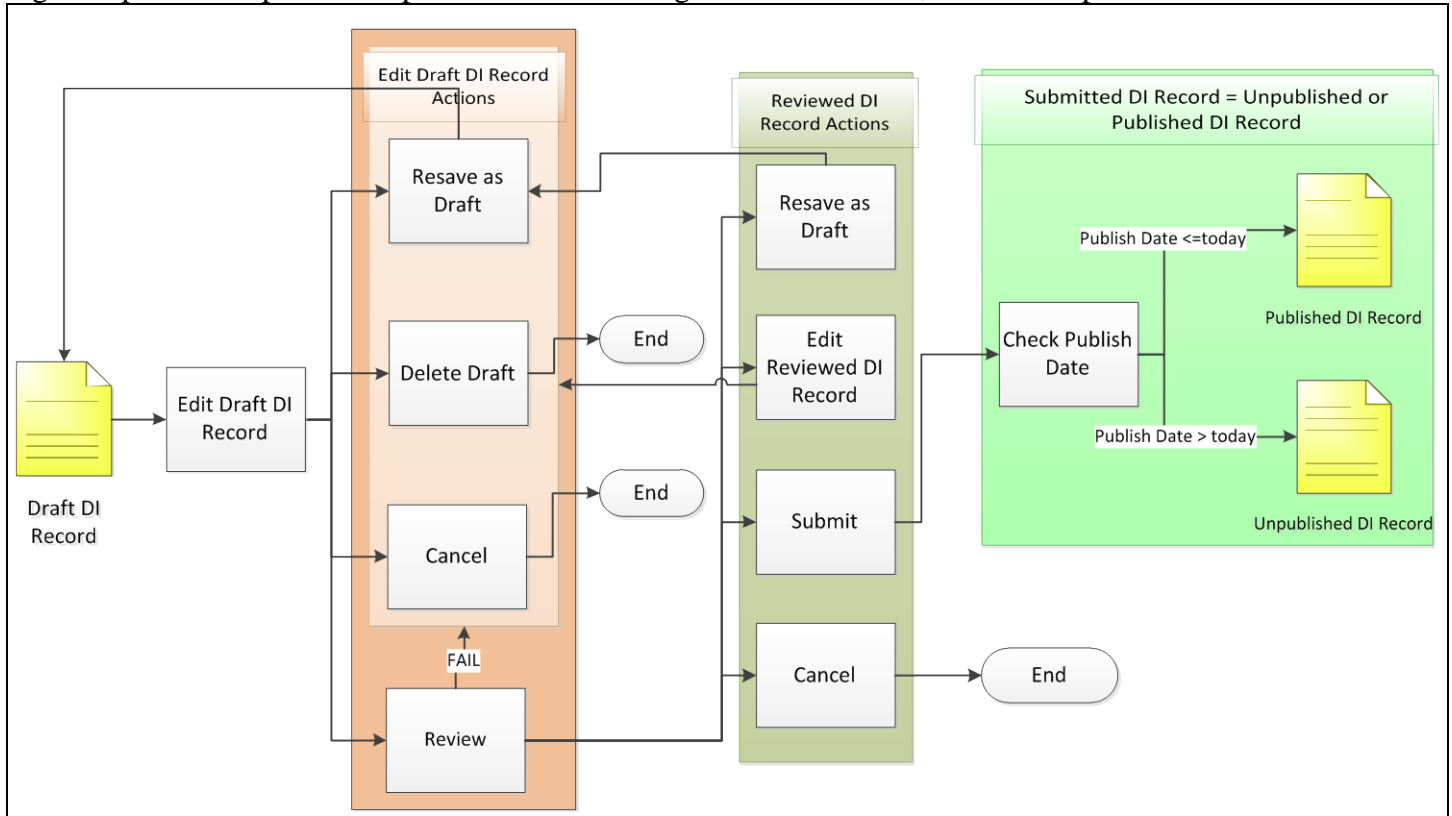


Figure 5: Editing a Draft DI Record

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.
 - Draft DI record can be saved in the system for 180 calendar days, after which it would be purged, i.e., permanently removed from GUDID.
 - 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 3.2.1.2.1, Creation of New DI Record, for details of the *Review* process.

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

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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	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	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

3.2.1.2.3 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:
 - during the grace period, all attributes, except *Publish Date* can be edited
 - after the grace period, editing would 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 would have limited editing capability.
 - See *Appendix B* for after grace period edit rules for all attributes.

Contains Nonbinding Recommendations

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
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

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In addition to editing Draft DI records as explained in Section 3.2.1.2.2, the LDE user can edit Unpublished or Published DI records and:

- *Review* the edited DI record to run GUDID business rules. See Section 3.2.1.2.1 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.

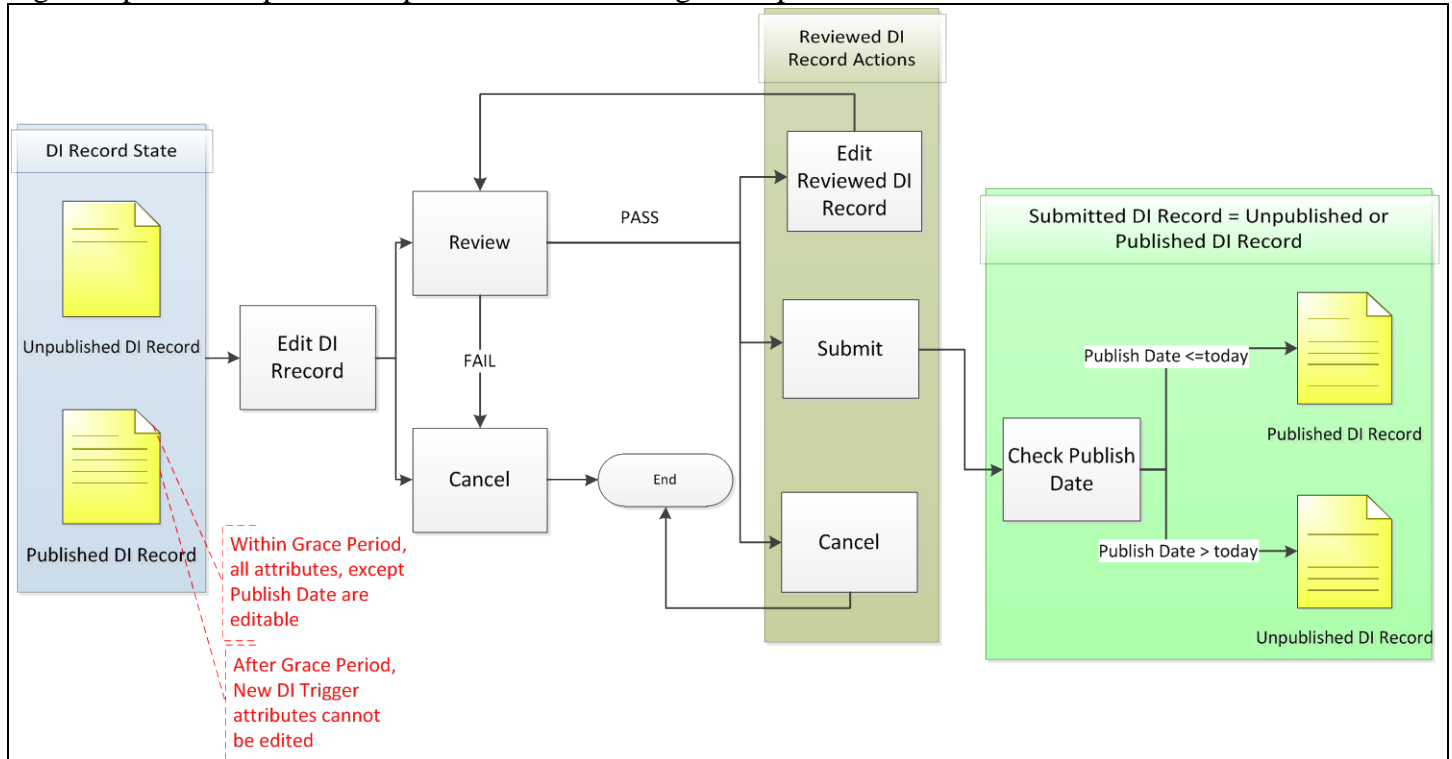


Figure 6: Editing an Unpublished or a Published DI Record

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.

3.2.1.2.4 COPYING DI RECORDS

Unpublished and Published DI records can be copied, however Draft DI records cannot.

- Copying enables the user to copy all attributes of a DI record to a new DI record, except for the Primary DI number¹¹. 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.

¹¹ Primary DI Number is the Device Identifier on the base package of a medical device.

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

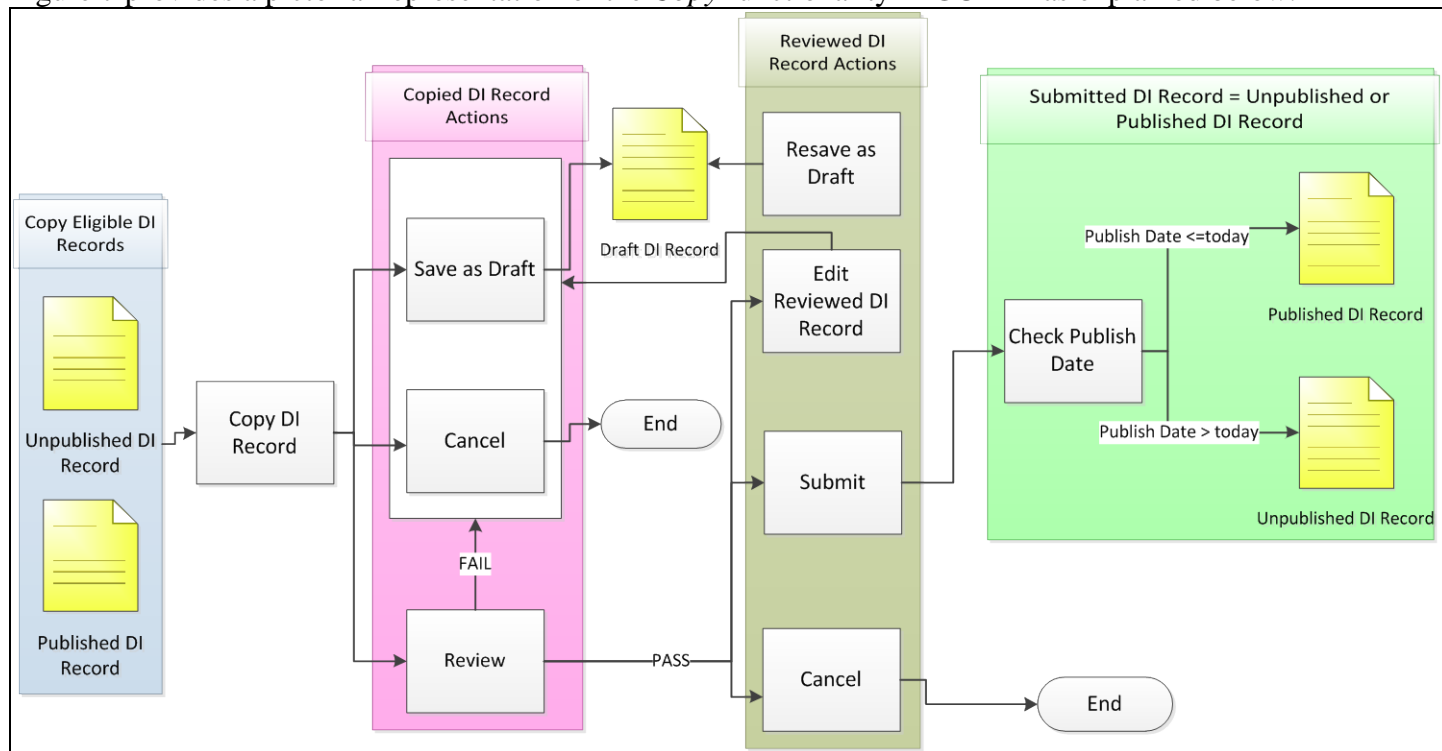


Figure 7: Copying DI Records

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 3.2.1.2.1 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. For detailed technical specifications on HL7 SPL submission option, please refer to the **Draft GUDID HL7 SPL Implementation Package**, 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 and Section 3.2.1.1 for details.
- 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 will be made available on <http://www.fda.gov/udi>

Contains Nonbinding Recommendations

- 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-parties to submit device information to GUDID.

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 the exception of a few such as: Labeler DUNS Number, Company Physical Address, GMDN Preferred Term Code, FDA Listing Number, etc.

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 via web service (download capability is planned for the future)

Please note that GUDID accounts would not be required for search or download 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 fields: Device Identifier, Company Name, Brand Name, and Model Number.
- Advanced Search – allows search on all GUDID attributes that are available for public search.

3.2.3.2 GUDID System to System Search and Retrieval via web service

GUDID will provide basic web service functionality to access published device information. Key characteristics of the web service are:

- Simple Object Access Protocol (SOAP) based web service accessible via HTTPS.
- The web service input will accept only one DI number per request. The following types of DI numbers are supported: Primary DI, Secondary DI, Unit of Use DI, Direct Marking DI, and Package DI.
- The web service will return attributes that are available for retrieval in XML format for the requested DI number type.
- Application errors or System errors will be returned as a SOAP fault. The following table lists standard HTTP errors:

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Error Code	Description
404	Not found
5XX	Server error. SOAP fault with internal server error

The Web Service Description Language (WSDL) for the web service will be made available when Public Search is enabled.

4 GUDID Submissions and 21 CFR 11 Requirements

21 CFR Part 11 requirements apply to GUDID submissions as follows:

Companies using the GUDID Web Interface: Electronic record systems provided by and maintained by FDA are not subject to 21 CFR 11 Requirements; therefore, users and submitters of electronic records utilizing FDA provided electronic record keeping systems would not be subject to 21 CFR 11 requirements.

Companies using the HL7 SPL option: Electronic record systems developed and utilized by labelers to meet record requirements as specified in 21 CFR 830.360 are subject to 21 CFR 11 requirements.

Companies using third-parties for GUDID submissions: The legal requirement to meet the 21 CFR 11 requirements is the responsibility of the labeler. Third-parties, submitting on behalf of device labelers, are not responsible to the FDA to meet the regulatory requirements of 21 CFR 11.

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 Examples

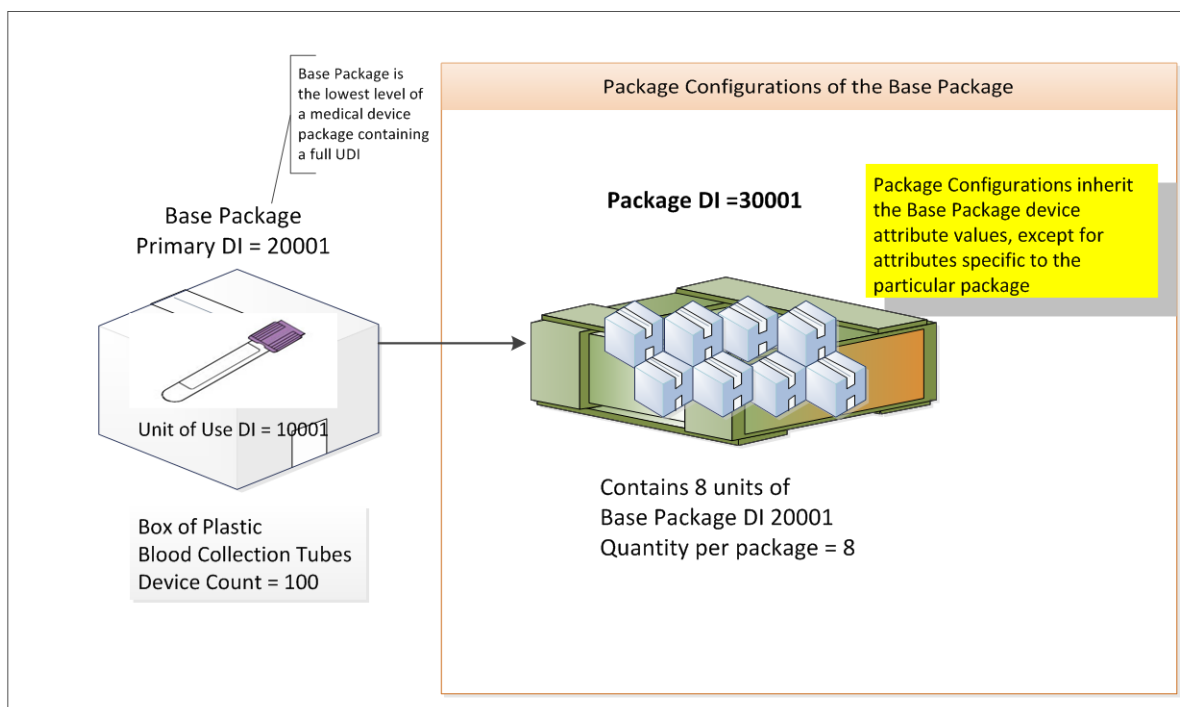
The examples below illustrate how package information is entered into the GUDID along with attribute values pertinent to packages.

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; therefore each tube gets a virtual *Unit of Use DI* 10001.
- Carton 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	Carton		In Commercial Distribution

Contains Nonbinding Recommendations

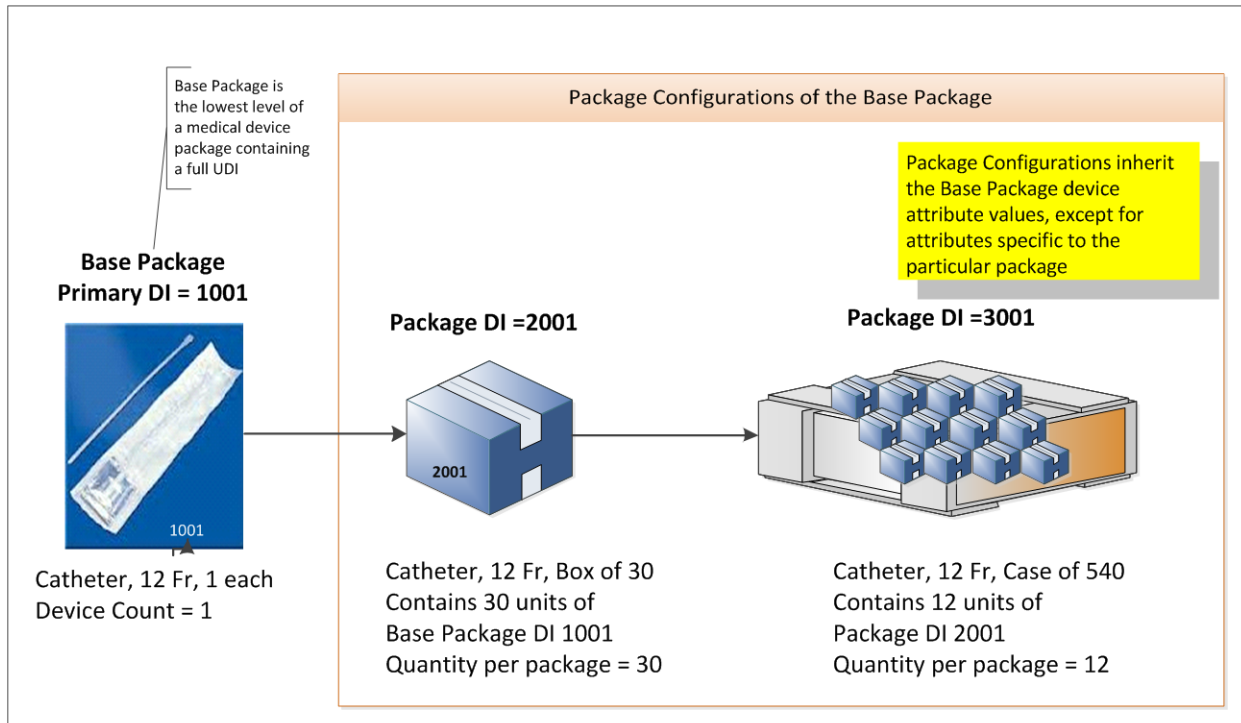
Figure 1: GUDID Package Configuration Example 1

EXAMPLE 2: DI ON INDIVIDUAL DEVICE + TWO 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).
- Carton of 12 boxes, with *Package DI* 3001 (contains 12 of *Package DI* 2001).
- *Package Discontinue Date* is blank, therefore system auto-populates *Package Status* to “In Commercial Distribution.”

Package 2001 and 3001 inherit all attribute values of base package 1001, except for the attributes specific to 2001 and 3001, 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	Carton		In Commercial Distribution

Figure 2: Package Configuration Example 2

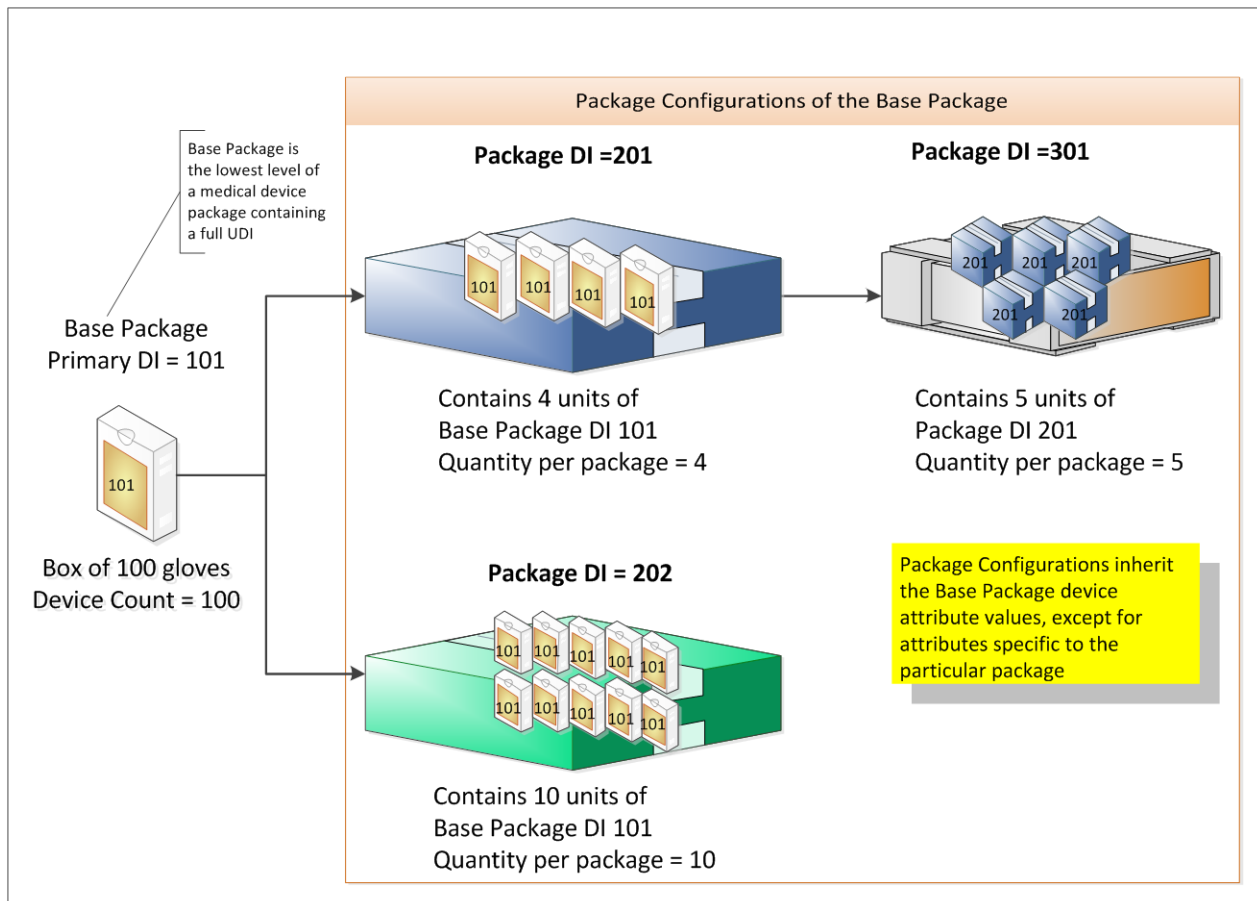
Contains Nonbinding Recommendations

EXAMPLE 3: DI NOT ON INDIVIDUAL DEVICE + MULTIPLE PACKAGING LEVELS

The figure below provides a package configuration example for GUDID where the DI is NOT on the individual device with multiple package levels.

- Gloves, box of 100, *Primary DI* 101 and *Device Count* = 100.
- Carton of 4, with *Package DI* 201 (contains 4 of *Primary DI* 101).
- Case of 5, with *Package DI* 301 (contains 5 of *Package DI* 201).
- Carton of 10, with *Package DI* 202 (contains 10 of *Package DI* 101).
- *Package Discontinue Date* is blank, therefore system auto-populates *Package Status* to “In Commercial Distribution.”

Packages 201, 301 and 202 inherit all attribute values of base package 101, except for the attributes specific to 201, 301 and 202, as shown in the table below.



Base Package

Primary Device Identifier	Device Count
101	100

Package DI

Package DI	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status
201	4	101	Box		In Commercial Distribution
301	5	201	Case		In Commercial Distribution
202	10	101	Carton		In commercial Distribution

Figure 3: Package Configuration Example 3

Contains Nonbinding Recommendations

Appendix B

The table below provides a list of GUDID attributes.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Device Information								
<u>Device Identifier (DI) Information</u>								
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs.	Choose a value from the drop down.	Cannot edit, add, or delete after Grace Period.	1..1 Required	Alphanumeric, 30	GS1; HIBCC; ICCBBA	YES	Public
Primary DI Number	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 number will be located on the base package, which is the lowest level of a medical device containing a full UDI.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	Cannot edit, add, or delete after Grace Period.	1..1 Required	Numeric or Alphanumeric, 6-23 characters	N/A	YES	Public
Device Count	Number of medical devices in the base package. For example, Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.	Enter a numeric value.	Cannot edit, add, or delete after Grace Period.	1..1 Required	Numeric, 7	N/A	YES	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Unit of Use DI Number	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.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value If Device Count =1, cannot add Unit of Use DI Number.	Can edit after Grace Period if Device Count > 1.	0..* Required if device count is greater than one	Numeric or Alphanumeric, 6-23 characters	N/A	NO	Public
Labeler DUNS Number	Business number issued by Dun & Bradstreet (D&B) that matches the Labeler (Company) name on device label.	Choose appropriate DUNS Number from drop down.	Can edit after Grace Period.	1..1 Required	Numeric, 9	from DUNS	NO	Private
Company Name	Company name associated with the labeler DUNS Number entered in the DI Record. This name should match the company name on the device label.	<i>System populated.</i>	Can be edited through D&B only.	1..1 Required	Alphanumeric	N/A	N/A	Public
Company Physical Address	Company physical address associated with the DUNS Number entered in the DI. This address should match the address on the device label.	<i>System populated.</i>	Can be edited through D&B only.	1..1 Required	Alphanumeric	N/A	N/A	Private

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Brand Name	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or TM symbol.	Enter the name of the device. Only the ® and ™ symbols will be supported for the production release.	Cannot edit after Grace Period.	1..1 Required	Alphanumeric and symbols, 80	N/A	YES	Public
Version or Model Number	The version or model number found on the device label or accompanying packaging used to identify a category or design of a device. The version or model means all devices that have specifications, performance, size, and composition, within limits set by labeler.	Enter an alphanumeric value.	Cannot edit after Grace Period.	1..1 Required	Alphanumeric and symbols, 40	N/A	YES	Public
Catalog Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.	Enter an alphanumeric value. No symbols are accepted.	Can edit, add, or delete after Grace Period.	0..1 Not Required	Alphanumeric and symbols, 40	N/A	NO	Public
Device Description (max 2000 characters)	Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.	Enter device description. Only the ® and ™ symbols will be supported for the production release	Can edit, add, or delete after Grace Period.	0..1 Not Required	Alphanumeric and symbols, 2000	N/A	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
<u>Commercial Distribution</u>								
DI Record Publish Date (mm/dd/yyyy)	Indicates the date the DI Record gets published and is available via Public Search.	Choose date from calendar or manually enter in format (mm/dd/yyyy). Cannot edit during or after Grace Period.	Cannot edit, add, or delete after Published.	1..1 Required	Numeric date format, 10	N/A	NO	Public
Commercial Distribution End Date (mm/dd/yyyy)	Indicates the date the device is no longer held or offered for sale. See 21 CFR 807.3(b) for exceptions. The device may or may not still be available for purchase in the marketplace.	Choose date from calendar or manually enter in format (mm/dd/yyyy).	Can edit, add, or delete after Grace Period.	0..1 Not Required	Numeric date format, 10	N/A	NO	Public
Commercial Distribution Status	Indicates whether the device is in commercial distribution as defined under 21 CFR 807.3(b).	<i>System populated.</i>	N/A	0..1 Required if record is published	N/A	In Commercial Distribution; Not in Commercial Distribution	NO	Public

Alternative or Additional Identifiers

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Direct Marking (DM)								
Device Subject to Direct Marking (DM), but Exempt	The device is exempt from Direct Marking requirements under 21 CFR 801.45.	Select checkbox if appropriate.	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A	NO	Public
DM DI Different from Primary DI	Indicates that the DM DI Number is different than the Primary DI Number.	Select checkbox if appropriate.	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A	NO	Public
DM DI Number	An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	Can edit, add, or delete after Grace Period.	0..* Required only if check box for 'DM DI Different from Primary DI'	Numeric or Alphanumeric, 6-23 characters	N/A	NO	Public
Secondary DI								
Secondary DI Issuing Agency	Name of Secondary DI Issuing agency.	Choose from drop down.	Cannot edit, add or delete after Grace Period	1..* Required if there is a Secondary DI Number	Alphanumeric, 30	GS1; HIBCC; ICCBBA; NHRIC	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Secondary DI Number	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI.	GS1- 14- digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value NHRIC- 10-digit numeric value.	Cannot edit, add or delete after Grace Period	1..* Required if there is a Secondary DI Number	Numeric or Alphanumeric, 6-23 characters	N/A	NO	Public
Package DI	Can add Package Configuration after Grace Period, but cannot delete or edit Package Configurations entered prior to the end of the Grace Period.							
Package DI Number	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers). For example: 4 glove boxes in a Carton -- Package DI =201 (the UDI on the Carton) 5 Cartons in a Case -- Package DI=301 (the UDI on the Case) contains a 5 cartons (with DI 201) with 4 glove boxes in a carton 10 glove boxes in a Carton -- Package DI=202 (the UDI on the Carton).	GS1- 14-digit numeric value HIBCC - 6-23 character alphanumeric value ICCBBA- 10 or 16 character alphanumeric value	Can add after Grace Period, but cannot delete.	0..* Not Required Required if Package Configuration is entered	Alphanumeric, 6-23 depending on Issuing Agency	N/A	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
<i>When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.</i>								
Quantity per Package	The number of packages with a unique primary DI within a given packaging configuration. For example: Package configuration Carton with Package DI=201 contains 4 boxes of the base package DI=101, the quantity per package is 4; Package configuration Case with Package DI=301 contains 5 cartons of Package DI=201, the quantity per package is 5. Package configuration Carton with Package DI=202 contains 10 boxes of the base package DI=101; the quantity per package is 10.	The quantity of a package configuration needs to be greater than 1.	Can add with new package configuration after Grace Period, but cannot delete	0..* Required if Package Configuration is entered	Numeric, 9	N/A	NO	Public
Contains DI Package	The primary DI for the base package or any lower level package configuration contained within a given package configuration. For example: Package DI=201 and Package DI=202 contain the base package Case with primary DI=101; Package DI=301 contains lower level package configuration of a Carton with Package DI=201.	Choose a value from the drop down.	Can add with new package configuration after Grace Period, but cannot delete	0..* Required if Package Configuration is entered	Alphanumeric, 6-23 depending on Issuing Agency	N/A	NO	Public
Package Type	Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations.	Free text.	Can add with new package configuration after Grace Period, but cannot delete	0..1 Not Required	Alphanumeric, 20	N/A	NO	Private

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Package Discontinue Date	Indicates the date this particular package configuration is discontinued by the labeler.	Choose date from calendar or manually enter in format (mm/dd/yyyy).	Can add with new package configuration after Grace Period, but cannot delete.	0..* Required if both Package Configuration and Commercial Distribution End Date are entered	Numeric date format, 10	N/A	NO	Public
Package Status	Indicates whether the package configuration is available or discontinued.	<i>System populated.</i>	N/A	0..* Required if Published	Alphanumeric	In Commercial Distribution; Not in Commercial Distribution	NO	Public
<u>Support Contact</u>								
Support Contact Phone	Phone number for the support contact.	Enter 10 digit North American number. For international numbers, start with "+" Does not require the use of () or -, but can enter these symbols.	Can edit, add, or delete after Grace Period.	1..* Required if support contact information is entered	Numeric, 20 (10)	N/A	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Support Contact Email	Email for the support contact.	Enter alphanumeric email address in format ---@---.---	Can edit, add, or delete after Grace Period.	1..* Required if support contact information is entered	Alphanumeric, 100	N/A	NO	Public
Device Status								
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3.	Check box if appropriate.	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A	NO	Public
Kit	Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as a medical device.	Check box if DI record is for the kit itself. Do not check if the product is part of a kit.	Cannot add or delete after Grace Period.	0..1 Not Required	Boolean	N/A	YES	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Combination Product	Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case.	Check box if DI record is for the combination product itself. Do not check if the product is a constituent part of a combination product.	Cannot add or delete after Grace Period.	0..1 Not Required	Boolean	N/A	YES	Public
Premarket								
Device Exempt from Premarket Submission	Device is exempt from FDA Premarket regulations; or a preamendment device.	Check box if appropriate.	Cannot add or delete after Grace Period.	0..1 Not Required Required if device is exempt from premarket submission	NO	N/A	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
FDA Premarket Submission Number	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.	Enter all valid FDA Premarket Submission Numbers.	Can add after Grace Period, but cannot delete or edit.	1..* Required Not required if Device Exempt from Premarket Submission is selected Not required for Kits Required for HCT/Ps	Alphanumeric, 8	N/A	NO	Public
Supplement Number	Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA, HDE, or PDP.	Enter all valid Supplement Numbers. Do not enter any alpha characters.	Can add after Grace Period, but cannot delete or edit.	0..1 Not Required unless Device contains Supplement. Not required if Device Exempt from Premarket Submission is selected. Not required for Kits.	Numeric, 4	N/A	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
<u>FDA Product Code</u>								
Product Code	Classification for pre-market devices issued by the FDA; three letter code.	Enter all applicable Product Codes.	Can edit, add, or delete after Grace Period.	0..* Required for all medical devices except for Kits or IVDs (BL premarket submission number)	Alpha, 3	FDA Product Code list	NO	Public
Product Code Name	Name associated with the three-letter Product Code.	<i>System populated</i>	N/A	1..1 Required with Product Code	Alphanumeric, 360	FDA Product Code list	NO	Public
<u>FDA Listing</u>								
FDA 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).	Enter all applicable Listing Numbers	Can add after Grace Period, but cannot delete or edit.	0..* Required for all medical devices except for HCT/Ps, Kits, and IVDs (BL premarket submission number).	Alphanumeric, 7	N/A	NO	Private
<u>GMDN</u>								
Code	Unique numerical five-digit code used to generically identify medical devices and related health care products.	Enter all applicable GMDN Preferred Term Codes.	Can edit, add, or delete after Grace Period.	1..* Required	Numeric, 5	GMDN list	NO	Private
Name	Name associated with the GMDN Preferred Term Code.	<i>System populated based on GMDN Preferred Term Code.</i>	N/A	1..1 Required	Alphanumeric	GMDN list	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Definition	Description associated with the GMDN Preferred Term Code.	<i>System populated based on GMDN Preferred Term Code.</i>	N/A	1..1 Required	Alphanumeric	GMDN list	NO	Public
Device Characteristics								
For Single-Use	Indicates that the device is intended for one use or on a single patient during a single procedure.	Choose a value from the drop down.	Cannot edit after Grace Period.	1..1 Required	N/A	Yes/No	YES	Public
<u>Production Identifier(s) on Label</u>								
Lot or Batch Number	Flag to indicate the device is managed by lot or batch number. This number can be found on the device label or packaging. Lot or Batch means one finished device or more that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.	Choose a value from the drop down.	Can edit after Grace Period.	1..1 Required	Boolean	Yes/No	NO	Public
Manufacturing Date	Flag to indicate the device is managed by date of manufacture; the date a specific device was manufactured.	Choose a value from the drop down.	Can edit after Grace Period.	1..1 Required	Boolean	Yes/No	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Serial Number	Flag to indicate the device is managed by serial number. This number can be found on the device label or packaging. The serial number is assigned by the labeler and should be specific to each device.	Choose a value from the drop down.	Can edit after Grace Period.	1..1 Required	Boolean	Yes/No	NO	Public
Expiration Date	Flag to indicate the device is managed by expiration date; the date by which the label of a device states that the device must or should be used.	Choose a value from the drop down.	Can edit after Grace Period.	1..1 Required	Boolean	Yes/No	NO	Public
<u>Latex Information</u>								
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing yes indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber".	Choose a value from the drop down.	Cannot edit after Grace Period.	1..1 Required	Boolean	Yes/No	YES	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Device labeled as "Not made with natural rubber latex"	Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container. Only applicable to devices not subject to the requirements under 21 CFR 801.437.	<p>Check box if appropriate.</p> <p>Only applicable if the response to "Device required to be labeled as containing natural rubber latex or dry natural rubber" was "No".</p>	<p>If selected "Yes" to "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)", cannot add or delete check to this field.</p> <p>If selected "NO" to "Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437)", can add or delete check to this field.</p>	0..1 Not Required	Boolean	N/A	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
<u>Prescription Status</u>								
Prescription on Use (Rx)	Indicates that the device requires a prescription to use.	Select check box if appropriate	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A	NO	Public
Over the Counter (OTC)	Indicates that the device does not require a prescription to use and can be purchased over the counter (OTC).	Select check box if appropriate	Can add or delete after Grace Period.	0..1 Not Required	Boolean	N/A	NO	Public
<u>MRI Safety Status</u>								
Is the device labeled for MRI Safety?	Indicates that sufficient testing has been conducted to characterize the behavior of the device in the MR environment. See ASTM F2503-13.	Check box if appropriate.	Can add check to checkbox after Grace Period, but cannot delete a check from the checkbox.	0..1 Not Required	Boolean	N/A	NO	Public
MRI Safety Status	Indicates the MR safety status of the device. The three drop down values are MR Safe, MR Conditional, and MR Unsafe. Please see the ASTM F2503-13 standard for more information on these three values.	Must select one value from drop-down if selected check box for "Has the device been evaluated for MRI Safety?"	Can add MRI Safety Status after Grace Period only if the field 'Has the device been evaluated for MRI Safety?' was previously unchecked. Cannot edit after Grace Period if 'Has the device	1..* Required if selected check box for "Is the device labeled for MRI Safety?"	N/A	MR Safe; MR Unsafe; MR Conditional	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
			been evaluated for MRI Safety?' was previously checked.					
<u>Clinically Relevant Size</u>								
Size Type	Dimension type for the clinically relevant measurement of the medical device.	Choose a value from the drop down.	Can add after Grace Period, but cannot delete or edit.	0..* Not Required Required if Size is provided	N/A	Circumference; Depth; Device Size Text, specify; French Catheter Gauge ; Greatest Diameter; Height; Length; Lumen Diameter; Needle Gauge; Second Greatest Diameter; Third Greatest Diameter; Total Volume; Width	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Size Value	Numeric value for the clinically relevant size measurement of the medical device.	Enter numeric value	Can add after Grace Period, but cannot delete or edit.	1..* Required if Size is provided	Numeric, 40	N/A	NO	Public
Size Unit of Measure	The unit of measure associated with each clinically relevant size.	Choose a value from the drop down.	Can add after Grace Period, but cannot delete or edit.	1..* Required if Size is provided	Numeric, 20	<u>For lengths:</u> Centimeter; Cubic Inch; Decimeter; Feet; Femtometer; French; Inch; Kilometer; Meter; Microliter; Micrometer; Millimeter; Nanometer; Picometer; Pint; Square Centimeter; Square Feet; Square Inch; Square Meter; Square Millimeter; Ton; Yard <u>For 'Total Volume':</u> Centiliter; Cup; Deciliter; Femtoliter; Fluid Ounce; Gallon; Kiloliter; Liter; Micrograms per Total Volume; Milligrams per Total Volume; Milliliter; Nanoliter; Picoliter; Quart; Units per liter	NO	Public
Size Type Text	Additional undefined device size not represented in the GUDID clinically relevant size list.	Enter size type text in addition to units.	Can add after Grace Period, but cannot delete or edit.	0..* Not Required	Alphanumeric (including symbols), 200	N/A	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
<u>Storage and Handling</u>								
Storage and Handling Type	Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure.	Choose a value from the drop down.	Can edit, add, or delete after Grace Period.	0..* Not Required Required if Storage and Handling is provided	N/A	Handling Environment Atmospheric Pressure; Handling Environment Humidity; Handling Environment Temperature; Special Storage Conditions; Storage Environment Atmospheric Pressure; Storage Environment Humidity; Storage Environment Temperature	NO	Public
Low Value	Indicates the low value for storage and handling requirements.	Must enter a Low Value and/or High Value if entering a Storage and Handling Type	Can edit, add, or delete after Grace Period.	0..* A Low Value and/or a High Value is required if Storage and Handling is provided.	Numeric, 6	N/A	NO	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
High Value	Indicates the high value for storage and handling requirements.	Must enter a Low Value and/or High Value if entering a Storage and Handling Type	Can edit, add, or delete after Grace Period.	0..* A Low Value and/or a High Value is required if Storage and Handling is provided.	Numeric, 6	N/A	NO	Public
Unit of Measure	The unit of measure associated with the storage and handling conditions. The unit of measure must conform to UCUM standards.	Choose a value from the drop down.	Can edit, add, or delete after Grace Period.	0..* Required if Storage and Handling is provided	N/A	Degrees Celsius; Degrees Fahrenheit; Degrees Kelvin; Kilo Pascal; Percent (%) Relative Humidity	NO	Public
Special Storage Conditions	Indicates any special storage requirements for the device.	Can enter alphanumeric with symbols	Can edit, add, or delete after Grace Period.	0..* Not Required Required if Special Storage Condition Text selected	Alphanumeric, 200	Free Text	NO	Public
<u>Sterilization Method</u>								
Device Packaged as Sterile	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.	Choose a value from the drop down.	Cannot edit after Grace Period.	1..1 Required	Boolean	Yes/No	YES	Public

Contains Nonbinding Recommendations

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period	Required?	Data Type & Length	Entry List of Values (LOV)	New DI Trigger?	Public/Private Status
When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label.								
Requires Sterilization Prior to Use	Indicates that the device requires sterilization prior to use.	Choose a value from the drop down.	Cannot edit after Grace Period.	1..1 Required	Boolean	Yes/No	YES	Public
Sterilization Method	Indicates the method(s) of sterilization that can be used for this device.	Choose a value from the drop down.	Can edit, add or delete after Grace Period only if 'Yes' was selected for 'Requires Sterilization Prior to Use' before Grace Period. Cannot add Sterilization Methods after Grace Period if 'No' was selected for 'Requires Sterilization Prior to Use' before Grace Period.	1..* Required if 'Requires Sterilization Prior to Use' is marked 'Yes'	N/A	Chlorine Dioxide; Dry Heat; Ethylene Oxide; High Intensity Light or Pulse Light; Hydrogen Peroxide; Microwave Radiation; Moist Heat or Steam; Ozone; Peracetic Acid; Radiation; Sound Waves; Ultraviolet Light	NO	Public

Appendix C

UDI Specifications by Issuing Agency

GS1® Issuing Agency¹²

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
1	(01)	DI	Numeric	16	14
GS1	(11)	Manufacturing Date	numeric [YYMMDD]	8	6
GS1	(17)	Expiration Date	numeric [YYMMDD]	8	6
GS1	(10)	Lot Number	Alphanumeric	22	20
GS1	(21)	Serial Number	Alphanumeric	22	20
GS1		Base UDI	Alphanumeric	76	66

Ex of Human Readable Barcode: (01) 5102222233336(11)141231(17)150707(10)A213B1(21)1234

The maximum number of characters in a database would be 66, while the maximum characters encoded in AIDC (barcode) would be 76. The parentheses are not encoded in the barcode. The difference is the removal of the digits in the Application Identifiers.

This max number of characters in AIDC would require either two GS1 128s or one GS1 DataMatrix

None of the other GS1 standardized symbologies could carry the total number of 76.

The average length for lot number is 7-9; the average length for serial number is 12.

¹² <http://www.gs1.org>

Health Industry Business Communications Council® (HIBCC) Issuing Agency¹³

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
HIBCC	+	DI	Alphanumeric	7-24	6-23
HIBCC	\$	Lot Number Only	alphanumeric	19	18
HIBCC	\$\$	Expiration Date followed by Lot Number	Exp Date: numeric [MMYY]	6	4
			Lot Number: alphanumeric	18	18
HIBCC	\$\$2	Expiration Date followed by Lot Number	Exp Date: numeric [MMDDYY]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	\$\$3	Expiration Date followed by Lot Number	Exp Date: numeric [YYMMDD]	9	6
			Lot Number: alphanumeric	18	18
HIBCC	\$\$4	Expiration Date followed by Lot Number	Exp Date: numeric [YYMMDDHH]	11	8
			Lot Number: alphanumeric	18	18
HIBCC	\$\$5	Expiration Date followed by Lot Number	Exp Date: numeric [YYJJJ] – Julian Date format	8	5
			Lot Number: alphanumeric	18	18
HIBCC	\$\$6	Expiration Date followed by Lot Number	Exp Date: numeric [YYJJJHH] – Julian Date format with Hour option	10	7
			Lot Number: alphanumeric	18	18
HIBCC	\$+	Serial Number only	alphanumeric	20	18
HIBCC	\$\$+	Expiration Date followed by Serial Number	Exp Date: numeric [MMYY]	7	4
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+2	Expiration Date followed by Serial Number	Exp Date: numeric [MMDDYY]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+3	Expiration Date followed by Serial Number	Exp Date: numeric [YYMMDD]	10	6
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+4	Expiration Date followed by Serial Number	Exp Date: numeric [YYMMDDHH]	12	8
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+5	Expiration Date followed by Serial Number	Exp Date: numeric [YYJJJ]	9	5
			Serial Number: alphanumeric	18	18
HIBCC	\$\$+6	Expiration Date followed by Serial Number	Exp Date: numeric [YYJJJHH]	11	7
			Serial Number: alphanumeric	18	18
HIBCC	/S	Supplemental Serial Number, where lot number <u>also</u> required and included in main secondary data string	alphanumeric	20	18

¹³ <http://www.hibcc.org>

Contains Nonbinding Recommendations

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
HIBCC	/16D	Manufacturing Date (supplemental to secondary barcode)	numeric [YYYYMMDD]	12	8
HIBCC		Base UDI	alphanumeric	70-87	58-75
Ex of Human Readable Barcode: +H123PARTNO1234567890120/\$\$420020216LOT123456789012345/SXYZ4567890123 45678/16D20130202C					
87 is the maximum possible data string encoded in the barcode, including the identifying symbols and the separator "/". The identifying symbols are not included in the database field size.					
The max possible data string is where expiry date is formatted as YYMMDDHH and the barcode includes a lot number and serial number and Manufacture date.					

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International Council for Commonality in Blood Banking Automation (ICCBBA) Issuing Agency¹⁴

Issuing Agency	Identifying Symbol	Identifier	Data type	Human Readable Barcode Field Size	Database Field Size
ICCBBA	=/	DI	alphanumeric	18	16
ICCBBA	=,	Serial Number	alphanumeric	8	6
ICCBBA	=	Donation Identification Number	alphanumeric	16	15
ICCBBA	=>	Expiration Date	numeric [YYYYJJ]	8	6
ICCBBA	=}	Manufacturing Date	numeric [YYYYJJ]	8	6
ICCBBA		Base UDI for HCT/Ps	alphanumeric	58	49
Ex of Human Readable Barcode: =/A9999XYZNN1T7049=,000025=A99971312345600=>014032=}013032					
ICCBBA	=)	DI for blood containers (bags)	alphanumeric	12	10
ICCBBA	&)	Lot Number for blood containers (bags)	alphanumeric	12	10
ICCBBA		Base UDI for blood containers (bags)	alphanumeric	24	20
Ex of Human Readable Barcode: =)1TE123456A&)RZ12345678					
Blood bags would have a different UDI format compared to HCT/P products regulated as a device; note that blood bags are being labelled with a DI Number and a lot number.					

¹⁴ <http://www.iccbba.org>

Appendix D

Many GUDID data attributes appear on the medical device label. When a GUDID attribute appears on the medical device package/label, the values submitted to the GUDID should match the value on the label. Figure D1 shows a fictitious medical device label and identifies the GUDID data attributes that appear on the label.

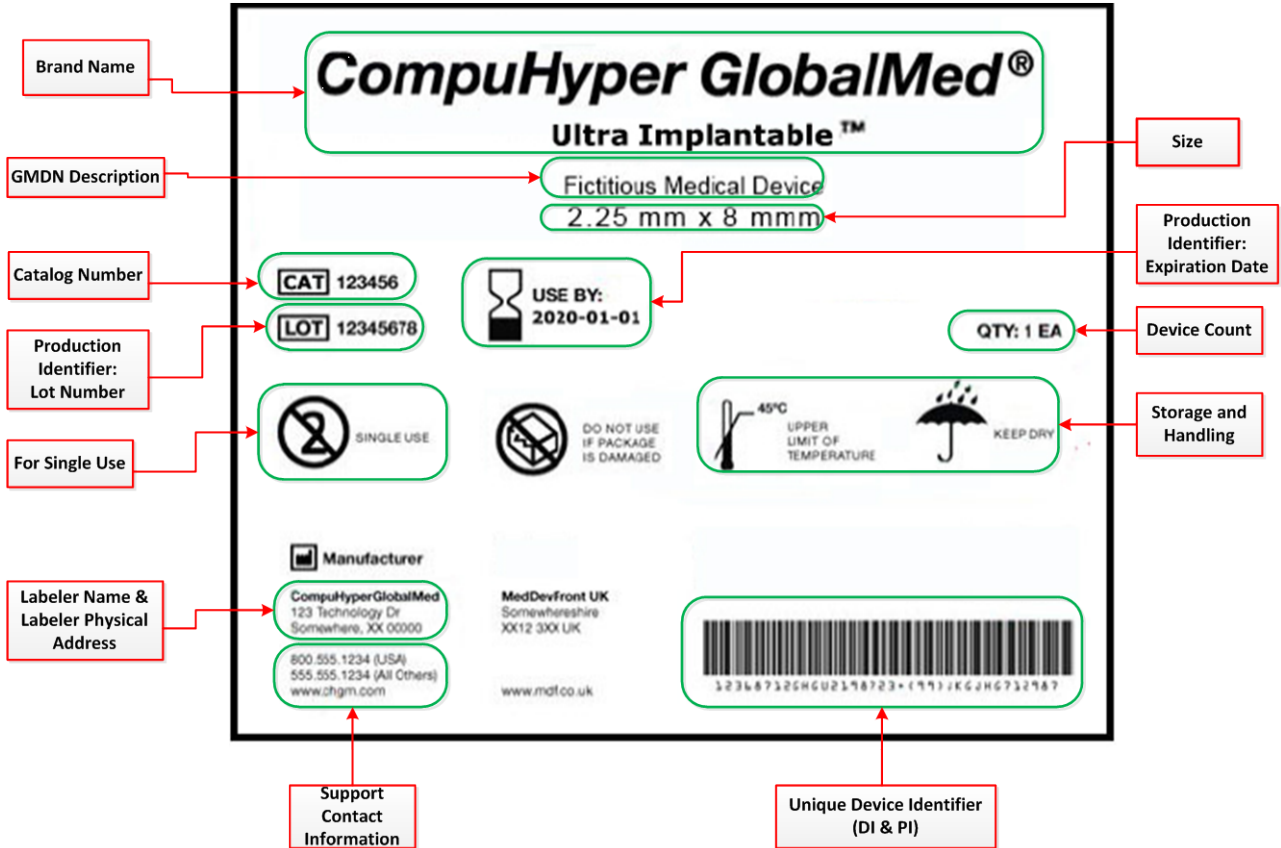


Figure D1: GUDID Attributes Mapped to a Fictitious Medical Device Label

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.
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.
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.
GUDID Web Interface	An online interface that enables secure account creation, secure submission of DI records, and search and retrieval of device information.

Contains Nonbinding Recommendations

Term	Description
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 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 will be located on the base package, which is the lowest level of a medical device containing a full UDI.
Product Code	Three letter classification code for pre-market devices issues by FDA.
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).

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Term	Description
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.
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.