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The GUDID

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Medical Device Forum

In the last Medical Device Forum, the author discussed the US Food and Drug Administration's new *Unique Device Identification (UDI) Final Rule* and the pending requirements upon medical device manufacturers. In that discussion, the Global Unique Device Identification Database (GUDID) was briefly discussed as well.

The FDA, Center for Devices and Radiological Health (CDRH), announced their long-anticipated *Unique Device Identification System Final Rule* on September 23, 2013, with the stated purpose "to establish a system to adequately identify devices through distribution and use." (1).

The UDI Final Rule requires the label of medical devices "to include a unique device identifier (UDI), except where the rule provides for an exception or alternative placement. The labeler must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID), unless subject to an exception or alternative. The system established by this rule requires the label and device package of each medical device to include a UDI and requires that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. The UDI will be required to be directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use." (1).

The UDI Final Rule is FDA's first step towards requiring regulated device manufacturers to implement a consistent way to identify medical devices throughout their distribution and use. This is part of a continuing effort to improve patient safety by making it harder to distribute counterfeit product and better facilitate the identification of problematic product in the field.

The discussion in this installment of Medical Device Forum will expand upon the GUDID as envisioned by FDA publications, with the majority of information taken from their GUDID Basics, referenced below (2).

The GUDID

The GUDID is to be a publicly searchable database to be administered by FDA. It will serve as a reference catalog for every device with an identifier. Per the UDI Final Rule, the labeler of each medical device labeled with a UDI must submit information concerning that device to the GUDID, with some exceptions.

According to the UDI Final Rule, "The labeler is the person who causes a label to be applied to a device, or who causes the label to be modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label; in most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler." (1).

However, the GUDID will only contain the device identifier (DI) portions of the UDI label. This DI will serve as the primary key

to obtain device information in the database. While production identifiers (PI) are not submitted to or stored in the GUDID, the GUDID will contain PI flags to indicate which PI attribute(s) are on the device label.

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

- GUDID Web Interface: Enables structured input of device information as one DI record at a time
- Health Level 7 (HL7) Structured Product Labeling (SPL) Submission: Enables submission of device information as XML files.

Either submission option will require the establishment of a GUDID Account (see discussion below). Initially, GUDID device information submissions will be open only to labelers of higher risk devices, currently marketed Class III medical devices and devices licensed under the *Public Health Service Act* (PHS Act).

The public will have access to information contained in the GUDID. There will be two information retrieval options for published DI information:

- Search and retrieval of device information via secure web interface
- System-to-system search and retrieval via web service.

Note: Download capability is planned for the future. GUDID accounts will not be required for search and retrieval of published information.

The GUDID will be populated with data about devices according to the compliance timeline in the UDI Final Rule. Currently, however, the public GUDID search function is temporarily disabled until a meaningful database of DI records has been created.

GUDID Draft Guidance

FDA issued the *GUDID Database Draft Guidance* on September 24, 2013 to provide preliminary information to labelers about submitting data. FDA announced that it plans for periodic GUDID Database enhancements to:

- Improve user experience
- Build in better validation rules
- Address other needs made known once the system is implemented.

Obtaining a GUDID Account

The initial step for labelers required to submit information to the GUDID is to request a GUDID account. As mentioned, GUDID accounts will initially be provided only to labelers of currently marketed Class III medical devices and devices licensed under the PHS Act.

The GUDID account identifies the labeler in the GUDID. An account is required regardless of the submission option chosen by the labeler, either the Web Interface or the HL7 SPL XML file option. The GUDID account is not organized submission type. A labeler does not need to have a separate GUDID account for each submission option.

Prior to Requesting a GUDID Account

Prior to applying for a GUDID account, labelers are encouraged to:

- Familiarize themsevles with the two submission options available: 1) The GUDID Web Interface and 2) the HL7 SPL XML file submission.
- Identify the Dun and Bradstreet® (DUNS®) Number(s) to be used to represent a GUDID account:
    - If a company does not have a DUNS® number(s), a company representative can obtain one free of charge from Dun and Bradsheet (D&B). This process may take up to 30 business days, so plan accordingly.
    - Expedited options to obtain a DUNS® number are available for a nominal fee.
    - See this website for more information.
- Ensure the organization name and address associated to the DUNS® number is correct. If any changes are necessary, update that information in the D&B DUNS® database accordingly before submitting to GUDID.

- Identify company individuals for the various user roles in GUDID:
    - Regulatory Contact: The company's existing designated Regulatory Affairs point-person;
    - Coordinator(s):
        - Manages the GUDID Account for assigned Labeler DUNS® numbers
        - Creates Labeler Data Entry User (LDE) accounts
        - Assigns Labeler DUNS® to LDEs
        - Coordinates accounts created by FDA Staff

      Note: The coordinator user role is not necessary for HL7 SPL only submitters

    - Labeler Data Entry (LDE) user(s):
        - Is responsible for day-to-day entry, submission, and management of device identification (DI) records
        - Has Labeler DUNS® assigned
        - Can only enter records for the assigned Labeler DUNS®;
        - Can see each others records for LDEs assigned the same Labeler DUNS®, except for drafts

      Note: LDE user role is not necessary for HL7 SPL only submitters.

    - Labelers that need to identify third-party submitters, if applicable. A third-party submitter is a company or individual selected by the labeler to act in their behalf on UDI / GUDID activities:
        - Web Interface Submitters may designate the third- party representative to act as Coordinator or LDE.
        - HL7 SPL submitters must identify their third party representative at the time of requesting a GUDID Account.

      Note: In either case, the third-party submitter is then to obtain a third-party DUNS® number, but only after ensuring that they have verified their information in the DUNS® database as accurate.

Requesting a GUDID Account

The following steps are involved for a company to request a GUDID Account:

1. Submit a GUDID New Account Inquiry to the FDA UDI Help Desk
2. The FDA UDI Help Desk will the email the GUDID Account Request document to the company in a fillable PDF format
3. The company representative will enter the requested information into the document
4. After completing the GUDID Account Request document, it can be e-mailed to the FDA UDI Help Desk as an e-mail attachment
5. Upon receipt of the completed document, an FDA Help Desk analyst will review the request and respond to the company within 10 business days
6. For all technical questions relating to accessing or setting up a GUDID account, a company should contact the FDA UDI Help Desk (4).

GUDID Web Interface

The GUDID Web Interface enables submission, search, and retrieval of device information via a secure web interface. To submit device information via the GUDID Web Interface, labelers must first obtain a GUDID account, as described above.

Note: The public GUDID search function is temporarily disabled until a meaningful dataset of DI records has been created.

The GUDID Web Interface can be found here.

GUDID Health Level 7 (HL7) Structured Product Labeling (SPL)

The HL7 SPL Submission option enables companies to electronically submit device information, one DI record at a time, as an HL7 SPL XML file.

HL7 is a non-profit, American National Standards Institute (ANSI) accredited standards development organization whose mission is to provide messaging standards for healthcare interoperability, exchange, management, and integration of data that

supports clinical patient care and the management, delivery, and evaluation of healthcare services.

Structured Product Labeling (SPL) is a HL7 standard for the exchange of product information using extensible markup language (e.g., XML). For GUDID, FDA will use the *HL7 SPL Release 5 Draft Standard for Trial Use* (DSTU) to receive device identification information.

Companies that plan to use the HL7 SPL submission option will need to do the following:

- Establish a GUDID account (as discussed above)
- Use the FDA Electronic Submissions Gateway (ESG) to submit HL7 SPL files: The Gateway can be found here
- Complete ESG account establishment and testing process
- Once GUDID and ESG accounts are established, companies will be required to complete GUDID testing prior to production submissions. Detailed information on testing requirements/process is provided in the HL7 SPL Implementation Files, located here

Conclusion

Confusing? Yes. Expect much additional information from FDA as these programs are implemented and problems arise. However, at this point in time, it is advisable that all medical device manufacturers review the information contained in this and previous Medical Device Forum articles on UDI and GUDID. Then, review the FDA's website (see references below) on UDI and GUDID and then implement a compliance plan based on company products and classifications as well as timelines and information presented in those resources.

References

1. FDA, *Unique Device Identification System Final Rule* (Rockville, MD Sept. 23, 2013), available here.
2. FDA, *GUDID Basics*, available here.
3. FDA, *Global Unique Device Identification Database Draft Guidance*, (Rockville, MD Sept. 23, 2013) available here.
4. FDA UDA Help Desk, available here.

General Reference

FDA's UDI Website, available here.

Acronyms

AIDC	Automatic Identification and Data Capture
ANSI	American National Standards Institute
CDRH	Center for Devices and Radiological Health
D&B®	Dun and Bradstreet® (see DUNS®)
DI	Device Identifier (device description, 1st component of the UDI)
DUNS®	Or D-U-N-S®; Dun and Bradstreet® Number (see D&B®)
ESG	Electronic Submissions Gateway
FDA	US Food and Drug Administration
GUDID	Global UDI Database
LDE	Labeler Data Entry
PI	Production Identifier
PHS	Public Health Service
SPL	Structured Product Labeling
UDI	Unique Device Identifier
XML	Extensible Markup Language

Also See:

- JVT: FDA's Unique Device Identification System Final Rule
- Regulatory Guidance: Software Validation
