Are you ready for UDI?

Achieve regulatory compliance, reduce recalls and improve patient safety in Life Sciences

In an effort to improve the quality of information in medical device adverse event reporting, reduce recalls and improve patient safety, in 2007 the United States Congress passed legislation directing the FDA to develop regulations establishing the unique device identification (UDI) system for medical devices.

The UDI provides for more efficient identification and characterization of medical devices, enhanced reporting, reviewing and analysis of adverse event reports, facilitating the capability that problem devices can be identified, isolated and corrected more quickly.

In an effort to drive harmonization globally, thereby providing a single globally accepted system for positive identification of medical devices, the US FDA, the European Commission, the International Medical Device Regulators forum (IMDRF) and other country regulators have established a dedicated working group to provide guidelines and a model for global UDI implementation making safety and integrity of the global healthcare supply chain a strategic priority. This will provide healthcare professionals (HCP) and patients with a single system to identify a device and its key attributes. The UDI provides a standardized identifier that will allow manufacturers, third party distributors and healthcare facilities to more effectively manage medical device recalls, providing a standard and clear way for healthcare facilities to document devices used in electronic health records, clinical information systems and registries.

The UDI is composed of two parts – DI and PI which make up the UDI:

- Device Identifier (DI) – Mandatory, fixed portion identifying a specific version/model and or model number of the medical device through its distribution and use.
- Production Identifier (PI) – Which contains manufacturing/production information of the device (e.g. lot or batch number, serial number of the specific device, expiration date and the date a specific device was manufactured).

Labeling

Every UDI codes must be printed on the label in both human readable and machine readable automatic identification and data capture format (AIDC) such as barcodes or RFID tags, and applied to the packaging of the device or on the device itself.

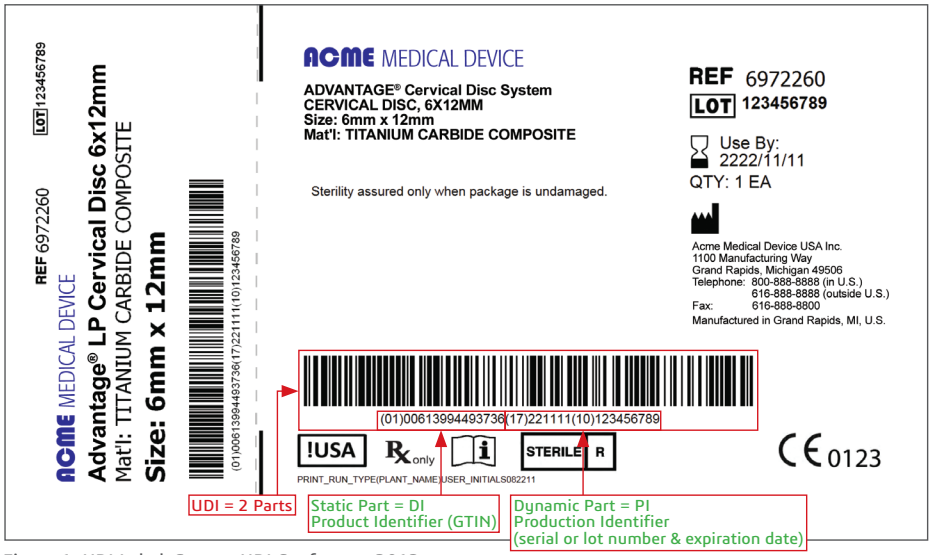

Figure 1. UDI Label. Source: UDI Conference 2012

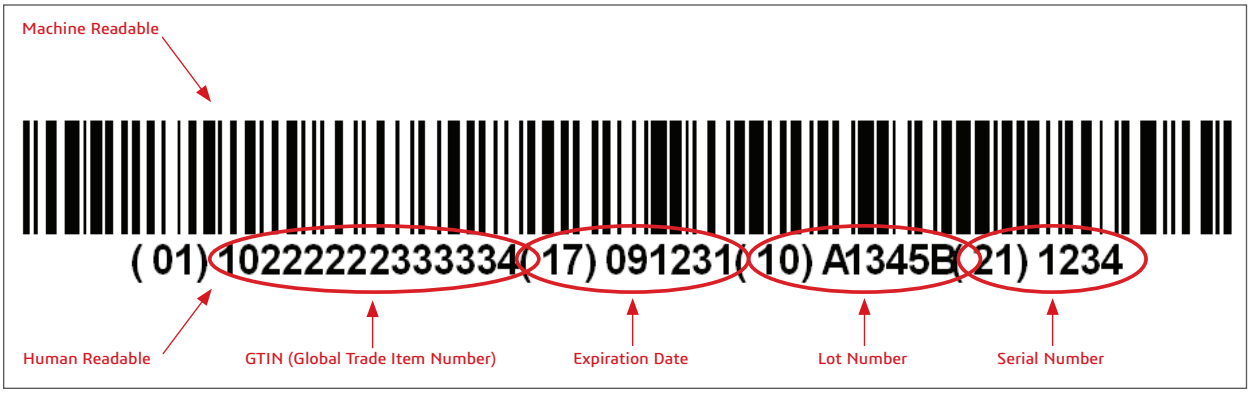

Figure 2. GTIN Healthcare Example. Source: GS1 Leveraging GS1 Standards & UDI, April 5, 2013

For some devices, specifically those that remain in use for an extended period of time (such as implantable devices), are sterilized routinely, or that may become separated from their original label, the rule would require the UDI information to be directly marked/etched on the device.

Additionally, certain combination products and their constituent parts, as well as convenience kits, will also require a UDI. The FDA has specified that a new UDI will be required in the event of a quantity change in packaging or when the model or version of a device changes.

Table 1. Current UDI Requested Attributes (Provisional)

- Primary Device Identifier (DI) (no control information)
- Secondary Device Identifier (if applicable)
- Unit of Use DI (if different from DI)
- Manufacturer's Name, Address & Contact Information
- GMDN
- Device Description
- Trade Name/Brand Name
- Model Number/Catalog Number (of DI & if part of a device family)
- Clinical Size (volume, length, gauge, etc)
- Storage Conditions
- Sterile?
- Sterilize prior to use, and method of sterilization
- Type of Control (PI) (serial number, Lot/Batch, Expiration Date, and/or manufacturer date) (not actual number or date)
- Can DI be reused?
- Contains Latex?
- Contains Human Tissue
- FDA Numbers
  - Product Code
  - Listing Number
  - Premarket Authorization, 510k, PMA
  - Supplement Number
- Direct Marking DI (if different from DI)
- Direct Marking Exemption Reason
- Marketing Status
- Is DI part of Kit? Or a Combination Item?
- DI Discontinued Date (if applicable)
- Higher Level Information

Source: GS1 Leveraging GS1 Standards & UDI, April 5, 2013

Implementation Dates

Implementation timeframe of the UDI is based upon premarket risk class of the device and will have to be implemented upon publication of final rule:

- Class III High Risk Implants & Life Sustaining Devices – 1 Year after final rule
- Class II Implants & Life Supporting/Life Sustaining Devices – 2 Years after final rule
- Rest of Class II Devices – 3 Years after final rule
- Class I Devices – 5 Years after final rule

Global Unique Device Identification Database (GUDID)

There are three major components to the UDI compliance:

- Labeling & Packaging
- Direct Part Marking
- Submission of UDI Data to the FDA GUDID

The GUDID database accessible to the public (HCP, regulators, patients) serves as a repository containing specific information about the UDI-labeled medical devices, specifically using the DI as the primary key to identify down to the model/version number of the device through their distribution and use. The DI and associated attributes (Table 2) are accessible via the GUDID database.

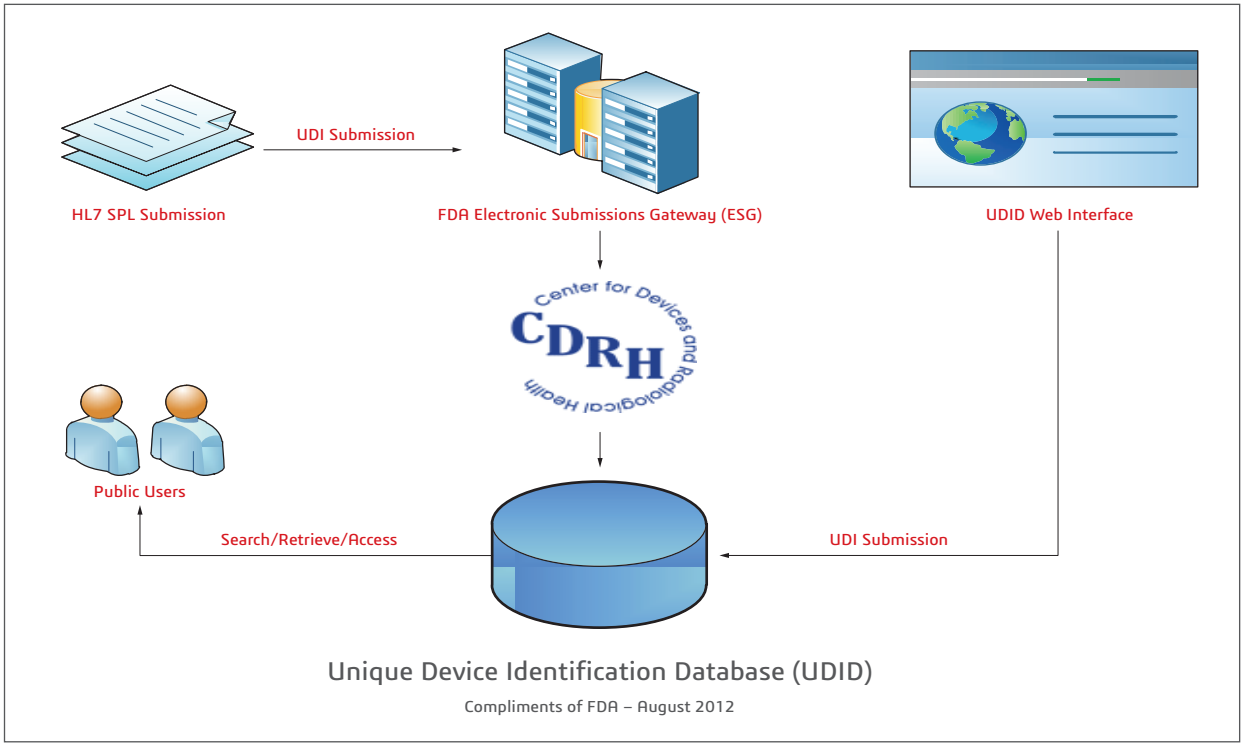

Figure 3. GUDID (UDI Database Overview). Source: GS1 Leveraging GS1 Standards & UDI, April 5, 2013

Table 2. Global UDID Database Attributes

DI Attributes

- Device Identifier Type/Code [GTN, HIBCC]
- Make/Model; Brand/Trade Name
- Clinically Relevant Size
- Device Version/Model No. (or Reference No.)
- Unit of Measure/Packaging Level/Quantity
- Controlled By – Lot and/or Serial Number; Expiration Date
- Labeler Contact Name, Phone, Email
- GMDN Classification Code/Term
- Whether Packaged Sterile
- Contains Latex
- FDA Premarket Authorization (510k, PMA)
- Listing Number

Administrative Attributes

- DUNS Number
- Brand Name or Model/Version – Device Family
- FDA Product Code (Procode)
- Marketing Status/Date
- For Single Use
- Contain Human Tissue
- Kit Product
- Combo Product
- Higher Level Packaging
- Rx – OTC

Source: MD&M February 2013 Presentation

Dassault Systèmes, Your Collaborator In Delivering a Global Enterprise Integrated UDI System Solution.

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