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Unique Device Identification and the AIM North America Healthcare Committee

The AIM North America Healthcare Committee is developing an extensive online UDI FAQ and Knowledge Base. See what's already there or ask YOUR question at http://www.aim-na.org/Healthcare_Committee.

About AIM North America

AIM North America is the industry trade association that represents the Automatic Identification Technology (AIT) industry in the US, Canada and Mexico. AIM North America provides education, news and information, legislative affairs, and marketing resources to grow the businesses of the industry's users, resellers, systems integrators, solutions providers, manufacturers, and distributors. AIM North America is a chapter of AIM, Inc., the worldwide authority on automatic identification and mobility for more than 40 years.

Association for Automatic Identification and Mobility

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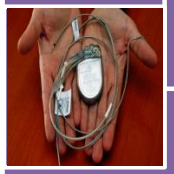
FDA's UDI Rule Impact on Manufacturers

Brought to you by the AIM North America Healthcare Committee





Association for Automatic Identification and Mobility

Unique Device Identification Summary

UDI is a United States FDA regulation that requires designated medical devices sold in the United States to adhere to certain standards of labeling. UDI also requires the recording of device attributes in a database called the Global Unique Device Identification Database (GUDID).

Impact To Manufacturers

The impact of UDI on medical device manufacturers will vary dramatically depending on the flexibility of their existing systems and the number of items which are subject to registration.

There are several areas which will require adoption, enhancement and capability. These can be divided into:

1. Selecting an FDA-accredited Issuing Agency
   a. Prospective candidates include:
      - GS1
      - HIBCC
      - ICCBBA
      - Others
2. Identifying a Database(s) to store UDI data
3. Assigning unique codes to all items - Maintaining, tracking, and reporting.
4. Labeling functionality:
   a. Linear (1-D Barcodes) and/or
   b. 2-D Barcodes and/or
   c. RFID and other AIDC technologies
5. Direct part marking
6. Communication with FDA Database GUDID – Non Proprietary data, device identification data only (no production-level data)

UDI Conventions

Medical Device Classes Equate To Patient Risk

Class III and Class II (CFR Title 21 part 860)
Device Identifier (DI) plus, (mandatory, if used by the manufacturer for identification)…

- Production Identifier (PI)
  - Lot/Batch
  - Exp Date
  - Prod Date
  - Serial Number

Class I (CFR Title 21 part 860)
Device Identifier (DI), and optionally…

- Production Identifier (PI)
  - Lot/Batch
  - Prod Date
  - Others

What Medical Devices Need to be Marked

A wide range of medical products can be marked, such as the following examples:

- Traditional hospital based devices (beds, ventilators, monitors, infusion pumps)
- Implants
- Patient/home use devices (glucometers)
- Disposables, accessories (glucose test strips, catheters)
- *In vitro* diagnostic devices (IVDs) – both clinical lab and Point of Care (POC)
- Health Information Technology (HIT)
- Convenience kits, combination products
- Those used in alternative sites – e.g., homecare, dental, etc.

Timeline* please refer to http://www.fda.gov/UDI

Class III

- UDI on Label and Package – September 24, 2014
- GUDID Interface – September 24, 2014
- Direct Part Marking – September 24, 2015 if implantable, life-supporting, and life-sustaining
- Direct Part Marking – September 24, 2016 if the following:
  - ✓ 1) A device intended to be used more than once and intended to be sterilized before each use, or…
  - ✓ 2) Stand-alone software regulated as a medical device

Not Class III but implantable, life-supporting, and life-sustaining devices

- UDI on Labels – September 24, 2015
- GUDID Interface – September 24, 2015
- Direct Part Marking – September 24, 2015 if implantable

Class II

- UDI on Label and Package – September 24, 2016
- GUDID Interface – September 24, 2016
- Direct Part Marking – September 24, 2015 if implantable, September 24, 2018 if the following:
  - ✓ 1) A device intended to be used more than once and intended to be sterilized before each use, or…
  - ✓ 2) Stand-alone software regulated as a medical device

Class I

- UDI on Labels – September 24, 2018 for class I medical devices and devices that have not been classified into class I, class II, or class III
- GUDID Interface – September 24, 2018, data for class I devices and devices that have not been classified into class I, class II, or class III
- Direct Part Marking – September 24, 2020 for class I devices and devices that have not been classified into class I, class II, or class III required to be labeled with a UDI permanent mark

Benefits of UDI

- Allows more accurate reporting, review and analysis of adverse event reports for problem device identification and remediation.
- Reduces medical errors by enabling rapid and precise identification of a device and important characteristic information.
- Enhances FDA analysis of devices on the market via a standard and clear way to document device use. A more robust post-market surveillance system can also be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- Provides standardized identifiers allowing manufacturers, distributors and providers to better manage medical device recalls.
- Creates a baseline for a global secure distribution chain, address counterfeiting, diversion of product, and prepares for medical emergencies logistics.
- Leads to the development of a medical device identification system that is recognized around the world.