Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.

*Niccolo Machiavelli (1523)*
Unique Device Identification (UDI) – Transforming the Global Medical Device Landscape

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History of FDA’s UDI Project

- 2007 FDA Amendments Act of 2007
- 2011 GHTF UDI Guidance published
- 2012 July 10th - UDI Proposed Regulation Publishes
- 2012 FDASIA provisions added
- 2012 November 7th – comment period closes
- 2012 November 19th – FDASIA amendment (Dec 19)
- 2013 June – expect UDI Final Rule
Legislation (FDAAA 07; FDASIA 12)

Not later than December 31, 2012, the Secretary shall issue proposed regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number. The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.
GHTF/IMDRF UDI AHWG

• Formed October 2008; EC Chair (Laurent Selles)
• Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA), Japan, Canada – and AHWP
• Final guidance approved September 2011
• General framework for any regulatory who wants to develop a UDI System
• Now morphed into IMDRF – work to continue
• Working on update to Sept 2011 Guidance – addressing issues raised in FDA UDI proposed rule and application to specific device groups/issues
UDI Proposed Regulations

Original Proposed Rule (July 10, 2012)
• Changes and additions to Part 801 Labeling
• New Part 830 – UDI Requirements
• Conforming Amendments

Amendment to proposed rule (November 19, 2012)
• FDASIA implementation timeframe
Date Format

• If label includes a date (expiration, manufacture):
• Presented as Month Day, Year (JAN 1, 2012)
• All dates must include a day (JAN 2012 not allowed)
• The month shown as a three letter abbreviation in capital letters: e.g., JAN, FEB, MAR
• Day is an number from 1-31
• Year is a 4 digit number

Effective 1 year after final rule publication
Establishing a UDI System

Combination of 4 distinct steps:

1. Develop a standardized system to develop the unique device identifiers (UDI)
2. Place the UDI in human readable and/or AutoID on a device, its label, or both
3. Create and maintain the UDI Database
4. Adoption and Implementation
1\textsuperscript{st} – Developing the UDI

- Develop UDI code according to ISO 15459 [GS1, HIBCC, ICCBBA]
- Created and maintained by the manufacturer
- Concatenating Device and Production Identifier
- Device Identifier (DI): [static] Manufacturer, make, model [i.e., each catalogue number]
- Production Identifier (PI): [dynamic] however product is currently controlled – serial, lot number; expiration, manufacturing date
2nd – UDI Application

- Unique UDI applied to “base package” AND higher levels of packaging
- Default location is the label
- Human readable and encoded in a form of automatic identification technology
- No specific technology (technology neutral)
- ALSO Direct Part Marking (DPM) for
  - an implantable device (>30 days)
  - intended to be used more than once, and intended to be sterilized before each use
  - stand-alone software
General Exemptions

- Class I Devices do not need to include Production Identifiers in UDI.
- Devices, other than prescription devices, made available for purchase at a retail establishments, (aka OTC devices, regardless of where distributed).
- GMP-exempt Class I devices
- Individual class I, single-use devices, all of a single version or model, that are distributed together in a single device package, which are not intended for individual sale – the UDI is on the package
- And others…
UDI Application Example
UDI Application Example
UDI Application Example

Donated Human Tissue

Human Allograft Tissue. Passes USP <71> Sterility Tests. Rx Only

DESCR: Demineralized Bone Strip

DIMEN: 5 cm x 5 cm
EXP: JAN 27, 2013
Store at ambient temperature. Do not freeze.

Treated with gamma radiation. Tissue is recovered under aseptic conditions. Tissue is aseptically processed and passes USP <71> Sterility Tests. Trace amounts of processing agents may remain. See package insert for these as well as for contraindications, warnings and preparation for use.

FOR SINGLE PATIENT USE ONLY

Generis Tissue Bank
Global Street
Any Town
Worldwide
Telephone: xxxxxxxx
Fax: xxxxxxxx
www.xxxxxx.org

ISBT 128
A999912123456
Processor: A9997
Product: T9017
Product Supplementary: Z012
Division: 102

ISBT 128 Area of Label
ISBT128

Device Identifier (Static): A9997T9017Z012
- A9997 is the processor identifier assigned by ICCBBA ≡ manufacturer identifier
- T9017Z012 is the product identifier ≡ catalogue number

Production Identifier: A999912123456102
- A999912123456 is the donation identification number ≡ Lot no.
- 102 is the division number ≡ serial number
Combination Products and Kits

• Combination product (PMOA is a device) has its own UDI; each device constituent needs its own UDI.
  • Except a CP that is physically, chemically, or otherwise combined with other parts of the CP such that it is not possible for the device constituent to be used except as part of the CP.
• Each kit (devices only) has its own UDI; each device packaged in a convenience kit shall have its own UDI, distinct from the kits.
  • Except – a device is intended for a single use does not need its own UDI
For Each Device Identifier:
- Labeler (DUNS), Make/model; Brand/Trade Name
- Clinically relevant size
- Device version/model number
- Catalogue/reference number
- Controlled by – Lot and/or Serial Number; Exp. Date
- GMDN and procode terms
- Whether packaged sterile
- Contains latex
- FDA premarket authorization; Listing number
- For single-use; Kit, Combo Product
- Higher levels packaging
3rd – Global UDI Database

Unique Device Identification Database (UDID) – Package Illustration

Package Configuration Examples

- **Base Package**
  - Primary DI = 001
  - Box of 100 gloves
  - Device Count = 100

- **Package DI = 002**
  - Contains 4 units of Base Package DI 001
  - Quantity per package = 4

- **Package DI = 003**
  - Contains 10 units of Base Package DI 001
  - Quantity per package = 10

- **Package DI = 004**
  - Contains 5 units of Base Package DI 003
  - Quantity per package = 5

Package configurations inherit the Base Package device attributes
FDA’s Global UDI Database

The label of Medical Device 123 Size 45:
- Device Identifier (Device XYZ123)
- Production Identifier (Lot #ABC)
- Expiration date (MMDDYYYY)
- Sterile; Latex free

Minimum Data Set
For each Device Identifier:
- Manufacturer and model
- GMDN Code
- Other attributes

Manufacturer (Acme)

3rd Parties (GDSN)

Web based tool

Bulk HL7 SPL

Distribution

FDA Managed

FDA

Business Rules

FDA’s UDI Database

Public User Interface
GUDID Draft “User’s Guide”

• Explain how interaction with the database will work:
  • Organizational module (DUNS structure, DUNS – match label, various user roles)
  • Device Identifier module/life-cycle, published records, grace period
  • Both web-base (UI) and HL7 SPL
  • Search
• Comments welcome
• Future training and database access
4th – Implementation

- Based on premarket risk class after publication of final rule:
  - class III – 1 year
  - class II implants and life-supporting/life-sustaining devices – 2 years
  - the rest of class II – 3 years
  - class I – 5 years
- Phase out national numbering system (NDC/NHRIC)
- Direct part marking requirements are effective 2 years after class effective date (except FDASIA)
What we have heard…

- Date format – ISO 8601 (YYYY-MM-DD) and with UDI implementation
- Existing inventory (stock, consignment) – some sort of extension/exception
- DPM – issues with implants
- OTC exemption – likely not as written – instead UPC be UDI for devices sold at retail (retail exception)
- Kits/combinations products – and combo kits
- Changes requiring a new DI – some changes (no tie to premarket)
Unique Device Identification
www.fda.gov/UDI
Email: cdrhudi@fda.hhs.gov
START NOW