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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United States of America

- Population of 314,585,000 (3rd most populous country)
- Total fertility rate 1.89 children/woman (<2.1)
- 82% residing in cities and suburbs
- CA, TX most populous states; NYC most populous city
- Average man 195 lbs (88.3 kg); woman 165 lbs (74.7 kg)
- Median age 36.8 years (male: 35.5, female: 38.1)
- Life expectancy at birth is 78.49, 50th in the world
- In 2009, spent $2.5 trillion, $8,047/person, on health care (17.3% of the GDP) – more than any other country
- Health insurance rising faster than wages or inflation.
History of FDA’s UDI Project

• 1999 IOM Report – To Err is Human
• 2004 FDA Pharmaceutical Barcode Rule
• 2005 and 2006 FDA/FDLI Meeting on UDI
• 2005 FDA Contracted White Papers on UDI
• 2006 Public Meeting and Docket FDA-2006N-0292
• 2007 FDA Amendments Act of 2007
• 2007-2009 – UDI Database Pilots
• 2008 GHTF Ad-Hoc Working Group on UDI
• 2009 UDI Workshop and Docket FDA-2008-N-0661
• 2011 GHTF UDI Guidance published
• 2012 FDA UDI Proposed Regulation Publishes
• 2012 FDASIA provisions added
• 2012 November 7th – comment period closes
• 2013 May – expect UDI Final Rule
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
UDI Proposed Regulations

1. Changes and additions to Part 801 Labeling
2. New Part 830 – UDI Requirements
3. Conforming Amendments
Definitions (1/2)

1. Combination product (21 CFR 3.2(e)) – includes a product comprised of two or more components, i.e., drug/device, biologic/device, or drug/device/biologic:
   - Physically, chemically, or otherwise combined or mixed and produced as a single entity
   - Two or more separate products packaged together in a single package or as a unit
   - A product packaged separately but intended for use only with another approved individual product

2. Convenience kit – two or more different types of medical devices packaged together
3. Implantable device – for UDI, is intended to remain implanted continuously for 30 days or more
4. Issuing agency – an organization accredited by FDA to operate a system for the issuance of UDIs
5. **Labeler** – one who applies or modifies the label with intent to put device into interstate commerce w/out any modifications
   - Except the addition of name, contact, etc for a distributor w/out making any other changes
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
1st – 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
2\textsuperscript{nd} – 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

PRESTIGE® Cervical Disc System
CERVICAL DISC, 6X12MM
Size: 6mm x 12mm
Mat'l: TITANIUM CARBIDE COMPOSITE

Sterility assured only when package is undamaged.
UDI Application Example

Finger-Mounted Locking Forceps

Manufacturer
T.A.G. Medical Products
Kibbutz Gaaton 25130 Israel
Tel: 972-4-9858400, Fax: 972-4-9858404

EU representative
MEDNET GmbH
Borkstrasse 10 48163 Muenster, Germany
Tel: +49 (251) 32266-0
Fax: +49 (251) 32266-22

Distributor
Ethicon Endo-Surgery Inc
Cincinnati OH 45242-2839 USA

Do not use if package is open or damaged
Single patient use only
Does not contain latex or PVC

STERILE R  RX Only
### UDI Application Example

The image shows a UDI (Unique Device Identifier) label, which includes various specifications and information for the device. Here are the key details:

**Manufacturer:** Bard Electrophysiology Division
C. R. Bard, Inc.
56 Technology Drive
Lowell, MA 01851

**Device Details:**
- **Reference:** 242406
- **Electrode Width:**
  - Proximal: 2 mm
  - Distal: 2 mm
- **Electrode Spacing:**
  - 2 mm
  - 9 mm
  - 2 mm
- **Cable:** 3 Easy-Mate* 8
- **No. of Electrodes:** 24
- **Length:** 110 cm
- **Lot Number:** XXXXXXXX
- **Expiration Date:** 2016–01

The label also includes barcodes, sterility and quality control symbols, and regulatory compliance information. This type of label is crucial for traceability and regulatory compliance in medical device manufacturing.
UDI Application Example

MOSAIC® 305 CINCH® II
Porcine Bioprosthesis Aortic Valve

Sterile LC: Device has been sterilized using Liquid Chemical Sterilants according to EN/ISO 14160.
Nonpyrogenic
Do Not Resterilize
Do Not Reuse
Rx only
For US Audiences Only
Consult instructions for use

Check temperature indicator prior to use

Manufacturer:
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Manufactured at:
Santa Ana, CA USA
© 2011 Medtronic
1211533002 Rev. 1B
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 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.
3rd – Global UDI Database

- Device Identifier Type/Code [GTIN, HIBCC]
- Make/model; Brand/Trade Name
- Clinically relevant size
- Device version/model number (or reference number)
- Unit of Measure/Packaging level/quantity
- Controlled by – Lot and/or Serial Number; Exp. Date
- Labeler contact name, phone, email
- GMDN Classification code/term
- Whether packaged sterile
- Contains latex
- FDA premarket authorization (510k, PMA)
- Listing number
3rd – Global UDI Database

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 levels packaging
- Rx - OTC
3rd – Global UDI Database

Unique Device Identification Database (UDID) – Package Illustration

Package Configuration Examples

- **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

Base Package
Primary DI = 001

Box of 100 gloves
Device Count = 100
FDA’s UDI Database

- **Manufacturer (Acme)**
- **Minimum Data Set**
  - For each Device Identifier:
    - Manufacturer and model
    - GMDN Code
    - Other attributes
- **3rd Parties (GDSN)**
- **Web based tool**
- **Bulk HL7 SPL**

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

FDA Managed

- **Business Rules**
- **FDA’s UDI Database**

Public User Interface

**Distribution**

**FDA**
4th – Implementation

- Based on premarket risk class after publication of final rule:
  - class III – 1 year
  - implants and 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
Conforming Amendments

- Part 803 – Medical Device Reporting
- Part 806 – Reports of Corrections And Removals
- Part 810 – Medical Device Recall Authority
- Part 814 – Premarket Approvals
- Part 820 – Quality System Regulation
- Part 821 – Medical Device Tracking Requirements
- Part 822 – Postmarket Surveillance
How to submit comments…

• Submit comments by November 7, 2012.
• Identify by Docket No. FDA-2011-N-0090 and/or RIN No. 0910-AG3.
• Submit written submissions by Fax: 301-827-6870.
• Comments on the Paperwork Reduction Act (PRA) must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB).
UDI MDEpiNet activities

- Develop roadmap on adoption and implementation of UDIs
- Develop clinically significant attributes for coronary stents and implement UDI based surveillance activities
- Develop clinically significant attributes for orthopedic devices
- Implement UDI based surveillance activities within the International Consortium of Orthopedic Registries (ICOR)
- ASTER-D - Incorporate UDI into Point-of-Care spontaneous electronic Adverse Event (AE) reporting
Unique Device Identification

www.fda.gov/UDI

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