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) – Enabling the Transformation of Medical Device Safety

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History of FDA’s UDI Project

- 1999 IOM Report – To Err is Human
- 2004 FDA 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
- 2011 Postmarket Surveillance and Compliance Workshop
- 2012 FDA 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.
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]
• 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 all levels of packaging, down to the lowest level (patient use/unit of use)
• 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
Risk-based Approach

- Production identifier reflects current control (label) – not requiring serialization.
- Not all devices require production identifiers
- Robust alternative placement and exception processes
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
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.

Medtronic

Prestige(TM) LP Cervical Disc 6x12mm
Mat'l: TITANIUM CARBIDE COMPOSITE
Size: 6mm x 12mm

(01)00613994493736(17)221111(10)123456789
0123

PRINT_RUNTYPE(PLANT_NAME)USERINITIALS022211

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone 800 633 2035 (in U.S.A.) 901 396 3133 (Outside U.S.A.)
Fax 901 396 0356
Manufactured in WARSAW IN US
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

EC REP
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
Rx Only

REF FMF02
LOT 1Q34
QTY 4

(01) 2 081019001 002 4
(17)080100(10)1Q34
UDI Application Example
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
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

3rd Parties (GDSN) or Web based tool or Bulk HL7 SPL

FDA Managed
Business Rules
FDA’s UDI Database

Public User Interface
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
Public Health Benefits

UDI/UDID provides global visibility and an easily accessible source of ‘master’ device data to improve:

• Medical device recalls
• Adverse event reporting
• Enhance safety assessments in surveillance and observational data sources
• Tracking and tracing
• Supply chain security; anti-counterfeiting/diversion
• Disaster/terror preparation
• Shortages/substitutions
• Reduction of medical errors (e.g., bedside scanning)
Clinical Impact of UDIs

• Inventory Control - Scanning devices at facility entry and maintaining UDI in the hospital information system would provide traceability (e.g., recalls)
• Documentation of use - Scanning the device when it is used on or in a patient
• Verification – Checking for device interactions– e.g., latex allergy, MRI compatibility, recalled devices
• Device Catalog - UDID provides National catalogue of ALL devices – find appropriate device, find comparable devices in cases of disaster or shortages/substitutions
Benefits of UDIs in EHRs

• Incorporating UDIs into EHRs would facilitate analysis of postmarket safety and outcomes data.
• Use in claims, EHRs, registries, and other electronic health-related data sources
• Facilitate AE reporting and assessing device-related adverse events and product problems
• Development of “Virtual Registries” (longitudinal tracking) to assess the risk/benefit and comparative safety/effectiveness in large populations
• Conduct of active surveillance for earlier detection of safety signals.
UDI for Postmarket Surveillance and Compliance Workshop

- Device identification in registries
- Comparative effectiveness
- Documenting medical device use in patient’s EHR/PHR, hospital information systems, and claims data
- Sentinel Initiative and other postmarket surveillance activities

- FDA Public Workshop on the Use of UDI for Postmarket Surveillance and Compliance – see www.fda.gov/udi
GHTF UDI ADWG

• Formed October 2008; EC Chair (Laurent Selles)
• Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA), Japan, Canada – and AHWP
• Washington April 2010; Brussels June 2010; Ottawa September 2010; May 2011
• Draft Guidance submitted to Nov 2010 SC meeting; released for public comments
• Final guidance approved September 2011
• Now morphed into IMDRF – more work to continue
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
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
CDRH Data Management (DM)

- UDID is Master Device Information
  - Source of Truth – data from UDI will be used throughout the healthcare eco-system
  - Safety Benefits - authoritative device information must be of highest quality and link to other Center data
- UDID – major part of CDRH DM Strategy
  - Apply DM Principles to UDID
  - Take advantage of rare opportunity to focus on Master Data Quality from the start of database implementation
UDI in HIT Data Sources

ONC/CMS/NQF

• Meaningful Use Stage 3
• Standards Development
  • UDI Use Case for Standards and Interoperability
    Public Health Reporting Initiative (S&I PHRI)
  • UDI as part of HL7 CDA – UDI
  • UDI as Vocabulary Standard for Certification
• Quality Measure Technical Evaluation Panel to assess readiness of UDI for quality measures
• UDI as part of Other HIT Measures
UDI in HIT Data Sources

• NCVHS Testimony - Claims Data
  • Description of CA UPN Pilot
  • Benefit of UDI for Safety
  • Allow UDI as X12/NCPDP Data Element
Unique Device Identification
www.fda.gov/UDI
Email: cdrhudi@fda.hhs.gov