# Establishment and Implementation of a Unique Device Identification System

National Committee on Vital and Health Statistics
June 20, 2012
Terrie Reed, Associate Director, Informatics
FDA, Center for Devices & Radiological Health

# Qualities of a UDI System

Develop a system to identify medical devices that is:

- Consistent
- Unambiguous (differentiates among all dimensions)
- Standardized
- Unique at all levels of packaging
- Harmonized internationally
- And facilitates the:
  - Storage,
  - Exchange, and
  - Integration of data and systems

# PostMarket Challenges solved by UDI

- *Adverse event reports*: Improve device identification and aggregation to improve signal detection
- *Recalls*: Improve timeliness and effectiveness of recalls
- *Registries*: Improve ability to collect device identifier information
- *Electronic health records*: Improve ability to document device use and document safety events

# Public Health Benefits

- Better data on actual product performance
- Improving FDA's use and understanding of adverse event reports
- Helping FDA to better understand the risk profile of particular devices
  - Allowing FDA to mine population-based data sets to better understand the risks and benefits of device use within certain patient populations and indications
  - In turn, this will allow FDA to better and more quickly address new concerns raised in premarket submissions

# UDI as Enabler

- Will unlock vast amounts of information, housed in a variety of data sources, on medical device performance – claims, Registries, Meaningful use
- Will facilitate linking across various data sources, thereby amplifying the utility of each

# Start: FDA Amendments Act of 2007

September 27, 2007, the FDAAA signed into law:

> The Secretary shall promulgate 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.

# Collaboration: Global Harmonization Task Force => International Medical Device Regulatory Forum

- Draft Guidance submitted to Nov 2010 SC meeting; released for public comments
- Final guidance approved September 2011 http://www.ghtf.org/ahwg/ahwg-final.html
- IMDRF – Implementation of UDI Roadmap proposed as work item for new forum: see www.imdrf.org

# Benefits of Global Harmonization

A globally harmonized approach to UDI can:

- Allow device manufacturers to apply and use a single UDI across a wide array of regulators
- Provide a foundation for a global, secure supply chain
- Facilitate global visibility/track and trace
- Allow for automated import review
- Facilitate global efforts to address counterfeiting and diversion
- Support DoD, WHO and other efforts requiring global device identification

# The Road to the Proposed Rule

The development consists of a number of steps:

1. Development of regulatory text (the legal language)
2. Development of preamble (the how and why)
3. Development of economic impact analysis
4. Approval by CDRH, FDA and then HHS
5. Approval by the Office of Management and Budget
6. Publication of proposed rule…

# And then the Final Rule

And then the fun begins…

1. 90 day comment period
2. Possible public meetings
3. Review and analysis of comments
4. Response to comments
5. Development of final rule (with responses)
6. Then  complete review again
7. And finally publication of the final rule

# Establishing a UDI System

Combination of 4 distinct steps – many stakeholders:

1. Develop a standardized system to develop the unique device identifiers (UDI) with certain characteristics
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 – UDI Characteristics

- 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

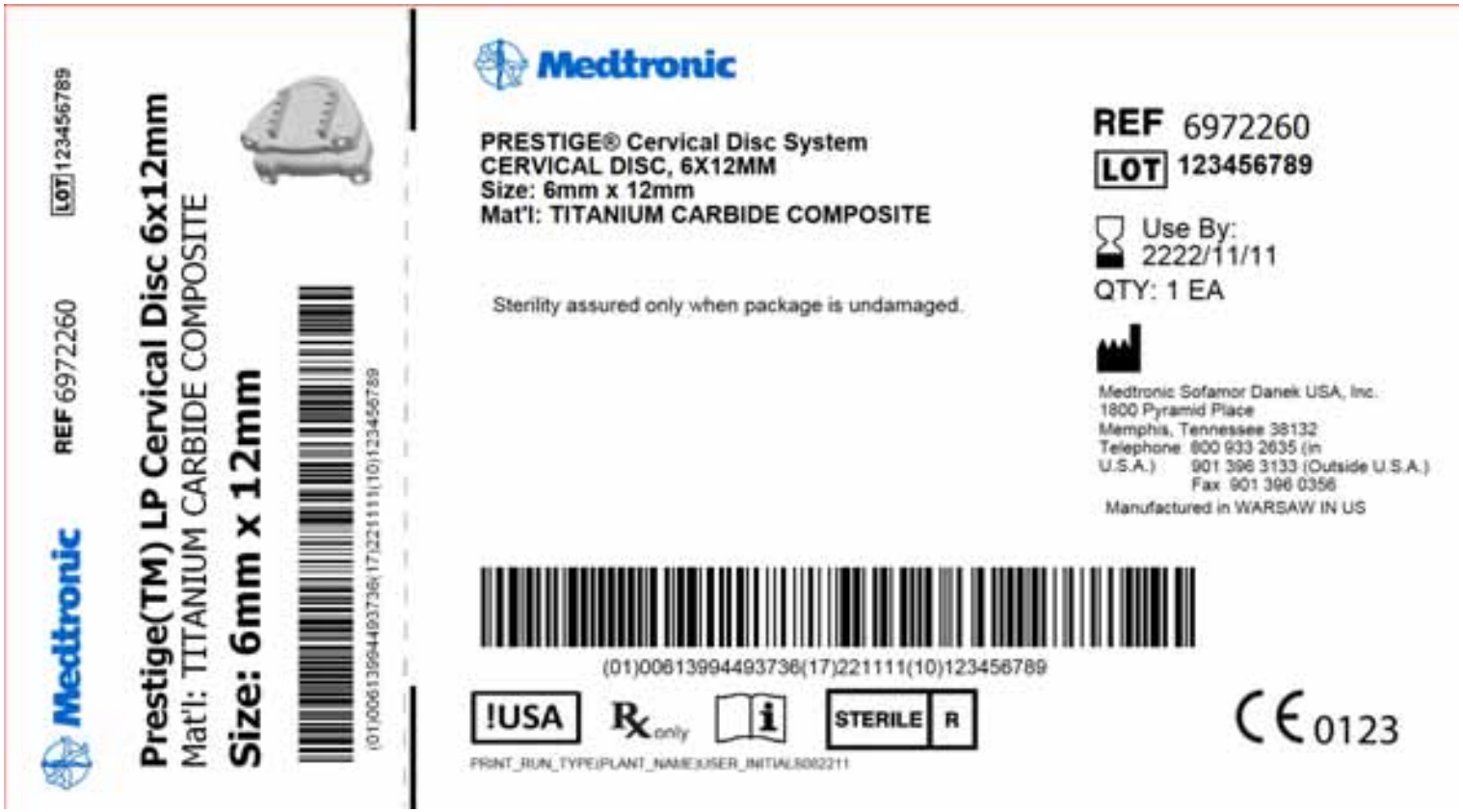
# 2nd – UDI Application

- Unique UDI applied to all levels of packaging, down to the lowest level (patient use/unit of use)
- Human readable and/or encoded in a form of automatic identification technology
  - No specific technology would be identified (technology neutral)
  - Identify a series of standards (linear barcode, 2-dimensional barcode, RFID)
  - Direct Part Marking (DPM) for some devices

# Risk-based Approach

- Production identifier reflects current control
- Granularity of marking based on risk of device -
  UDI for some devices on multi-packs or higher levels of packaging
- Not all devices require production identifiers
- Take into account realities of retail environment
- Robust alternative placement and exception processes

# UDI Application – Three Examples



# UDI Application Example

ENDOPATH®
dextrus™
Finger-Mounted
Locking Forceps

REF FMF02 LOT 1Q34
080100 QTY 4

(01) 2 081019001 002 4

(17)080100(10)1Q34

T.A.G.
CE 0344

**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

ETHICON ENDO-SURGERY, INC.

**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

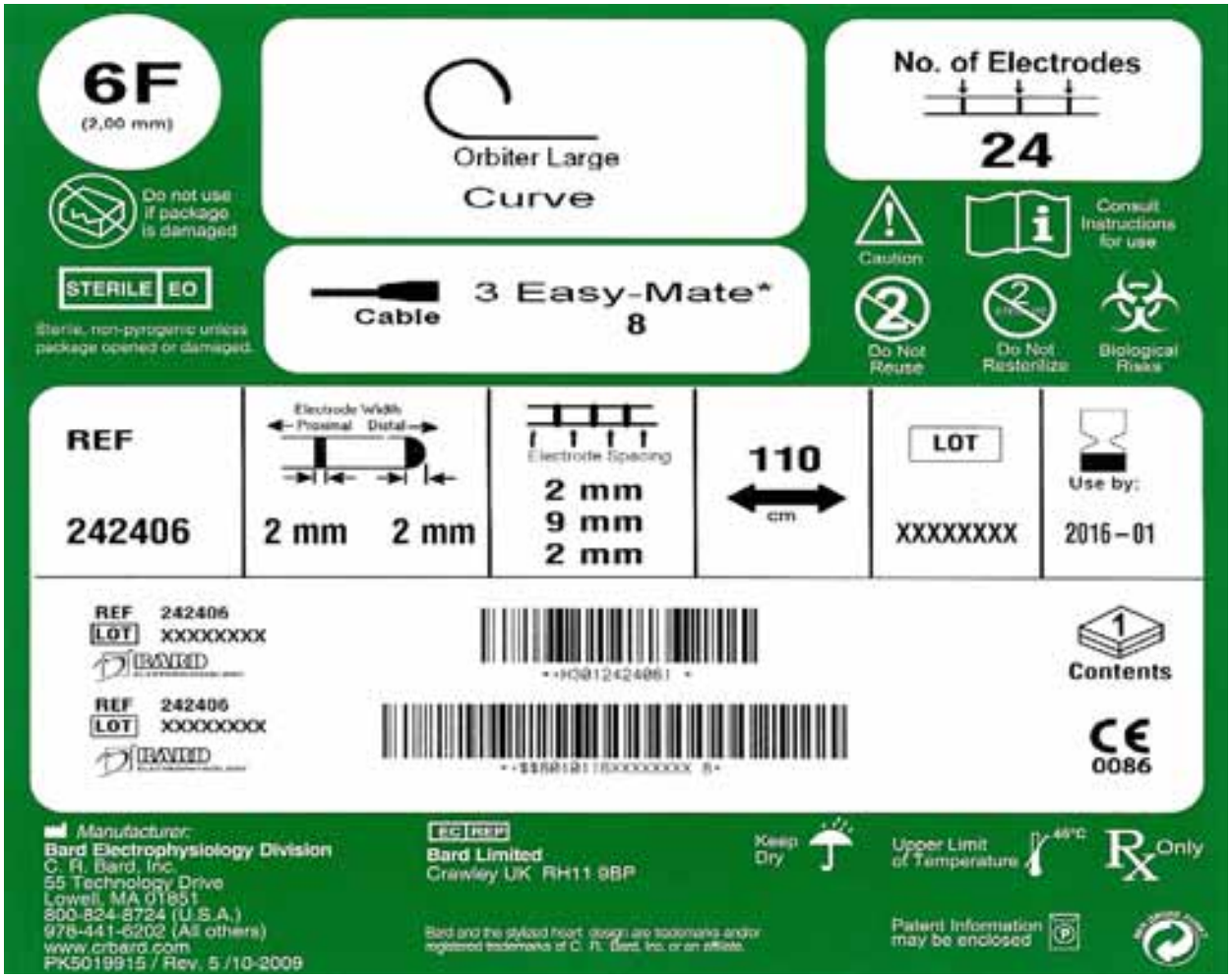
STERILE R
℞ Only

D1SOFFL802 Rev D

ENDOPATH®
dextrus™
Finger-Mounted
Locking Forceps

REF FMF02

# UDI Application Example



# 3rd – Global UDI Database

Attributes from IMDRF--

- Device Identifier Type/Code [GTIN, HIBCC]
- Make/model; Brand/Trade Name; Size; Description
- Device model number (or reference number)
- Unit of Measure/Packaging level/quantity
- Controlled by – Lot and/or Serial Number; Exp. Date
- Contact name, phone, email
- GMDN Classification code/term
- Storage condition; Single Use; Sterility
- Contains known, labeled allergen (e.g., latex)

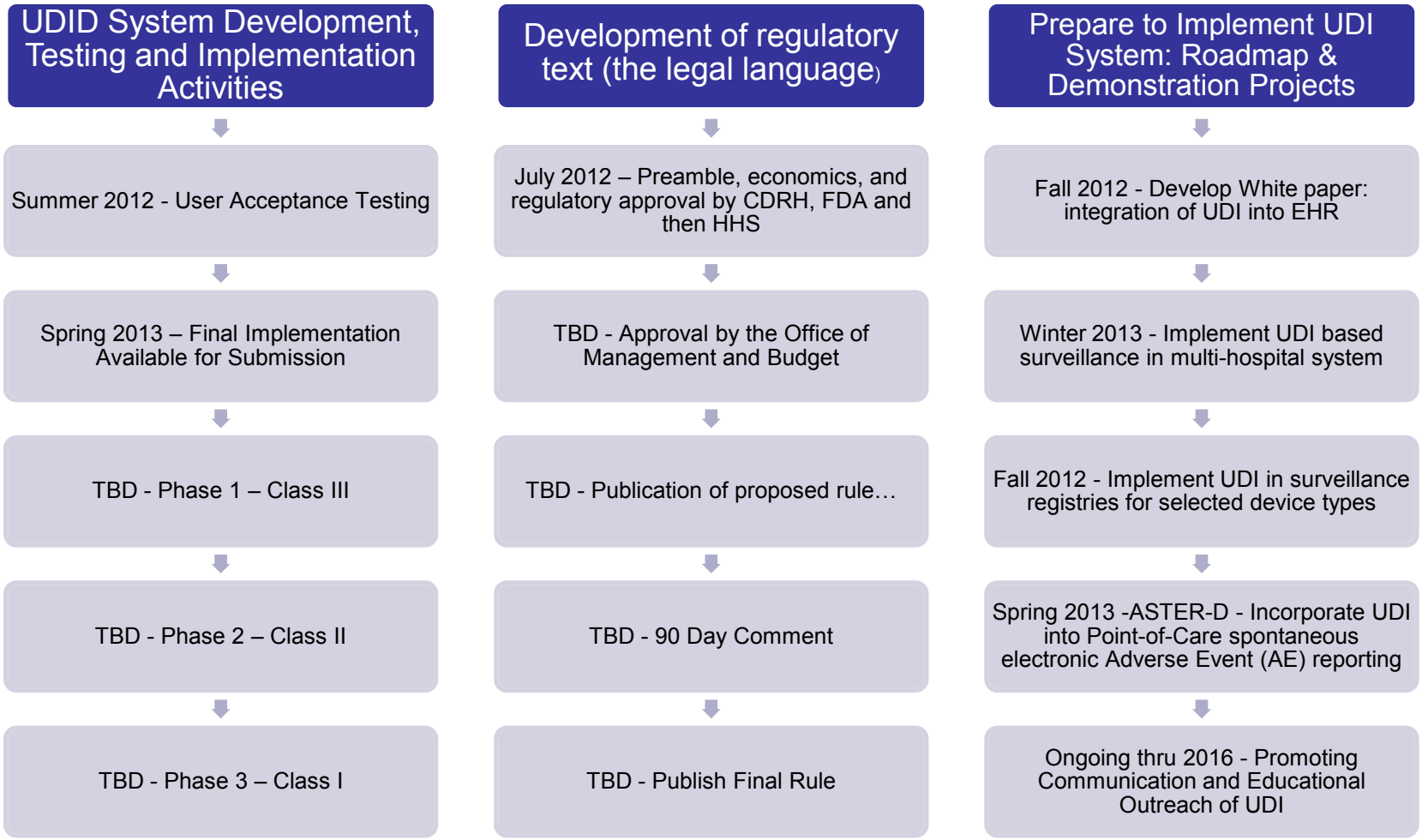
# 4th – Implementation

- Based on premarket risk class:
  - Class III – 12 months after final rule (implants)
  - Class II – 36 months after final rule (equipment)
  - Class I – 60 months after final rule (disposables)
- Allows stakeholders to jointly learn and for mid-course corrections
- Phase out national numbering system (NDC/NHRIC)
- Robust alternate placement and exception process

# Integration of UDI to Improve Postmarket Surveillance

- White papers - Develop papers on various aspects of implementation of UDIs in health-related electronic records including claims, registries, EMRs, etc
- Implement UDI-based surveillance activities focused on various device types into multi-hospital systems
- ASTER-D - Incorporate UDI into Point-of-Care spontaneous electronic Adverse Event (AE) reporting

# Summary of UDI System Timelines



# Unique Device Identification

www.fda.gov/UDI

Email: cdrhudi@fda.hhs.gov