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

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

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

Definitions (2/2)

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

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

Medtronic

REF 6972260

LOT 123456789

Prestige(TM) LP Cervical Disc 6x12mm

Mat'l: TITANIUM CARBIDE COMPOSITE

Size: 6mm x 12mm

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

Medtronic

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

Sterility assured only when package is undamaged.

REF 6972260

LOT **123456789**

Use By:
2222/11/11

QTY: 1 EA

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone 800 933 2635 (in U.S.A.)
901 396 3133 (Outside U.S.A.)
Fax 901 396 0356

Manufactured in WARSAW IN US

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

!USA Rx only STERILE R

CE 0123

PRINT_RUN_TYPE(PLANT_NAME)USER_INITIALS082211

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. MEDICAL PRODUCTS
ת.א.ג. מכשירים רפואיים

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.
a Johnson & Johnson company

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

0-45

D150PPLB02 Rev.D

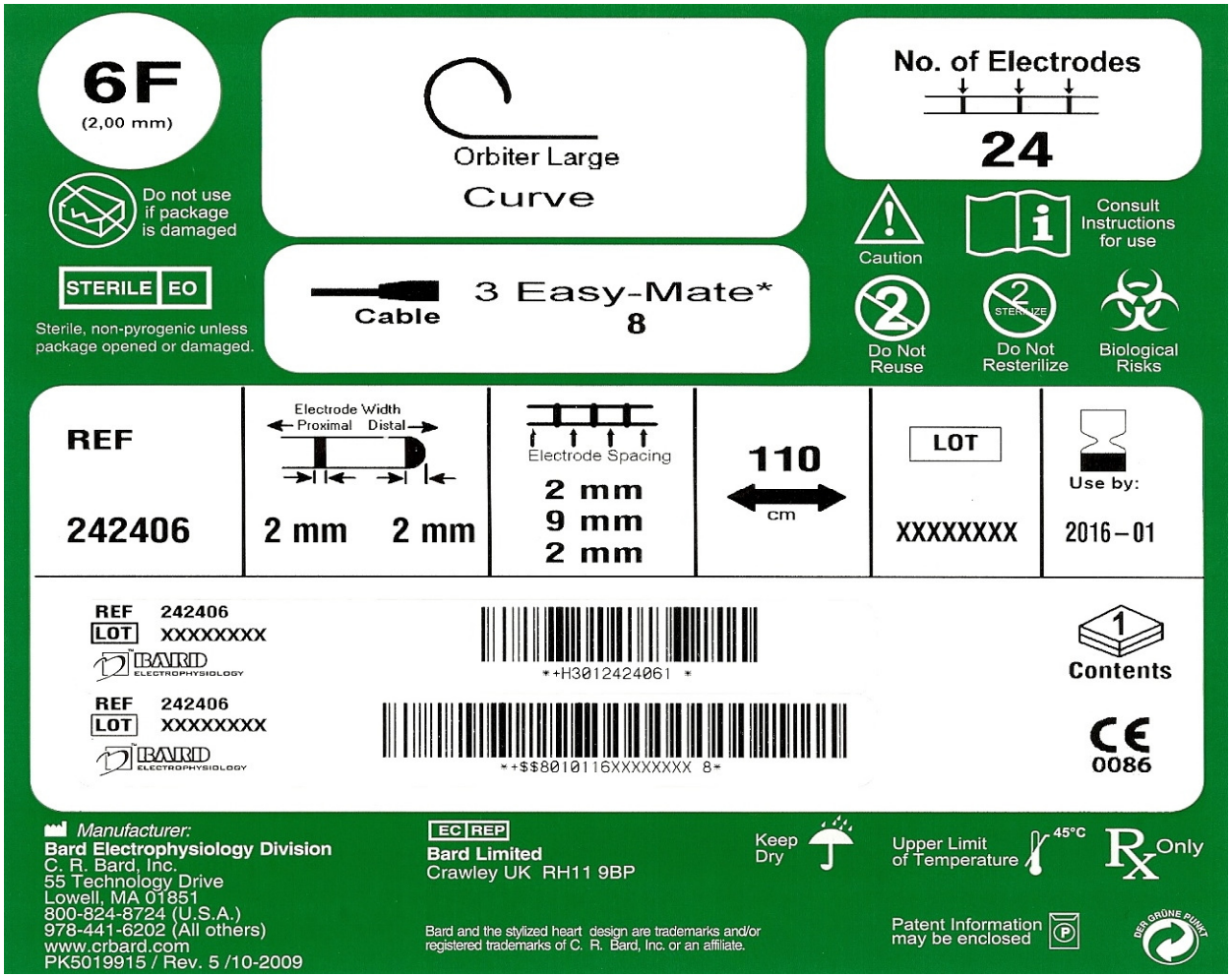
ENDOPATH®

dextrus™

Finger-Mounted
Locking Forceps

REF	FMF02

UDI Application Example



UDI Application Example

MOSAIC® 305 CINCH® II

A

21 MM

REF Reorder Number → 305C221

Size → 21 MM

Use By → 2016 – 07 – 12

SN Serial Number → 21A11F4855

(01)00643169001763(17)160712(21)21A11F4855

MOSAIC® 305 CINCH® II

Porcine Bioprosthesis Aortic Valve

AOA®

Aortic

(01)00643169001763(17)160712(21)21A11F4855

STERILE LC

Sterile LC: Device has been sterilized using Liquid Chemical Sterilants according to EN/ISO 14160.

PYROGEN

Nonpyrogenic

2 STERILIZE

Do Not Resterilize

Do Not Reuse

: 1

Quantity

+5 °C +41 °F +25 °C +77 °F

Temperature Limitation

! USA Rx only

For US Audiences Only

www.medtronic.com/manuals

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

1211533002 Rev. 1B

MOSAIC® 305 CINCH® II

Porcine Bioprosthesis Aortic Valve

AOA®

Aortic

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

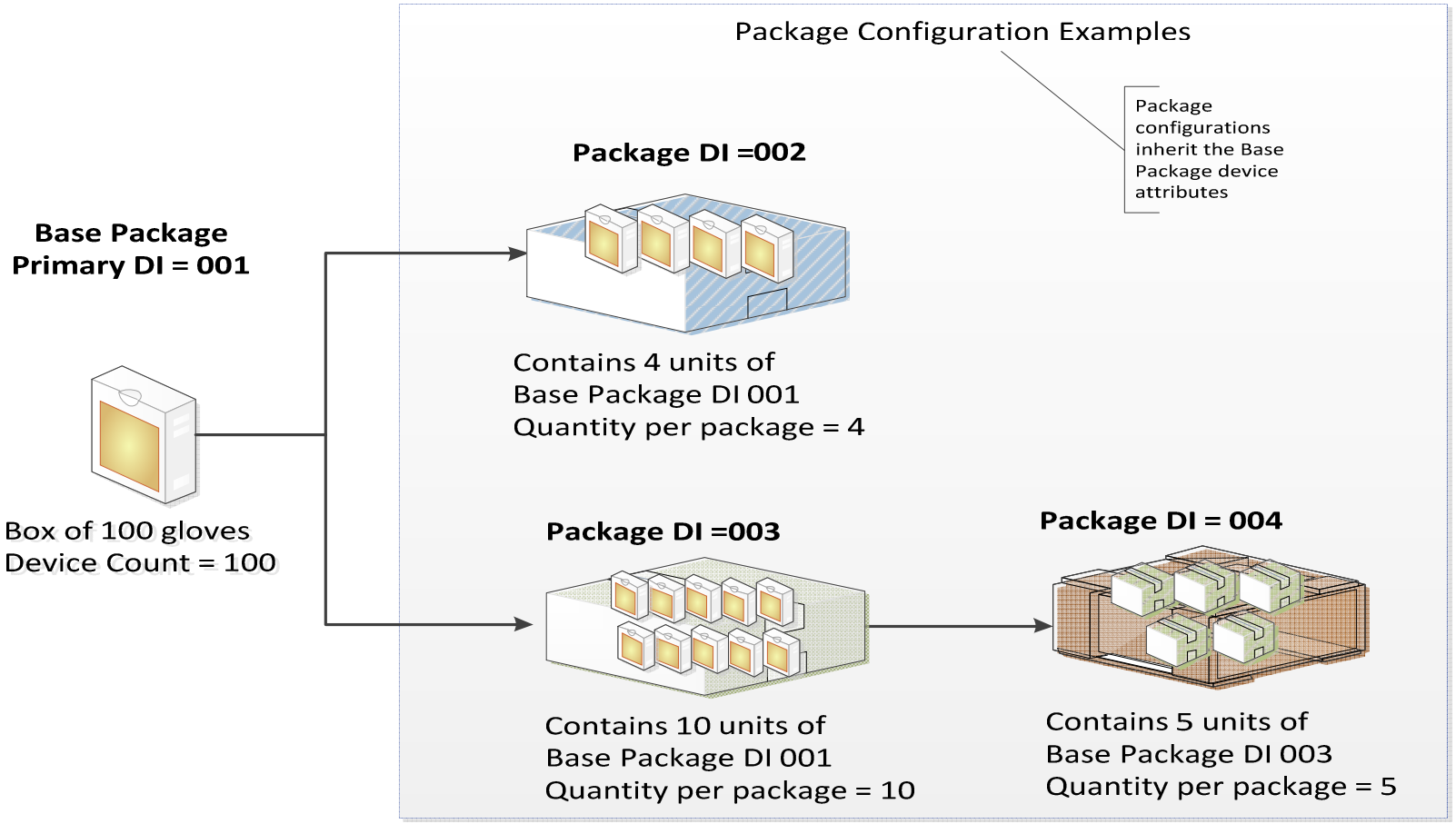
3rd – Global UDI Database

Administrative attributes:

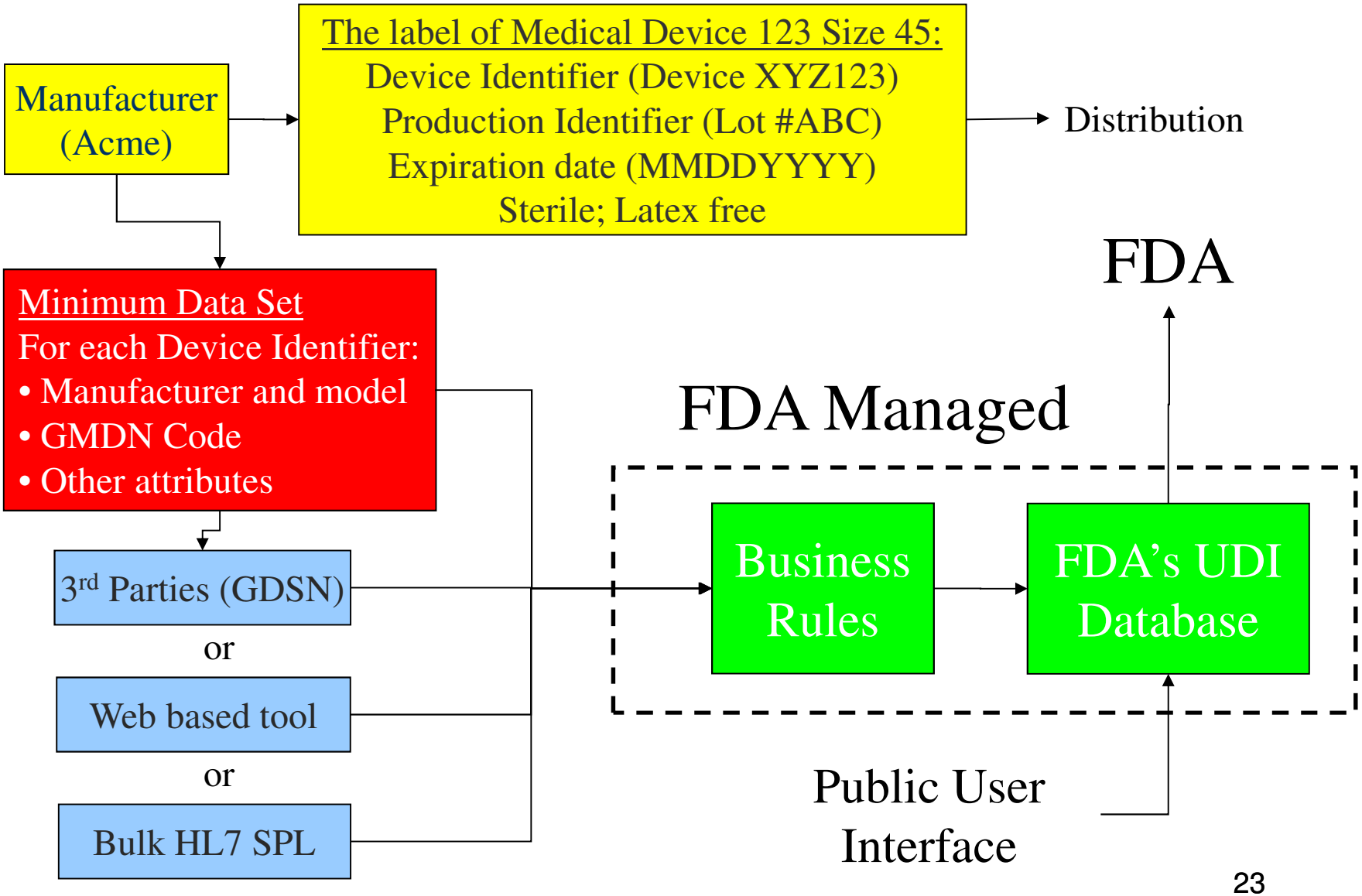
- DUNS Number
- Brand Name or Model/Version – Device Family
- FDA product code (procode)
- Marketing Status/date
- For single-use
- Contain Human Tissue
- Kit Product
- Combo Product
- Higher levels packaging
- Rx - OTC

3rd – Global UDI Database

Unique Device Identification Database (UDID) – Package Illustration



FDA's UDI Database



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 electronic comments to the Federal eRulemaking Portal: http://www.regulations.gov.
- 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

Email: cdrhudi@fda.hhs.gov