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

Jay Crowley
Senior Advisor for Patient Safety
Food and Drug Administration
jay.crowley@fda.hhs.gov
301-980-1936

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

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

MOSAIC® 305 CINCH® II

A

21 MM

REF → 305C221
Reorder Number

Size → 21 MM

Use By → 2016 – 07 – 12

SN → 21A11F4855
Serial Number

(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

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

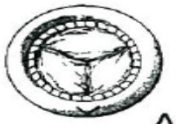
Manufacturer:
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Manufactured at:
Santa Ana, CA USA

1211533002 Rev. 1B

MOSAIC® 305 CINCH® II
Porcine Bioprosthesis Aortic Valve

AOA®



Aortic

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

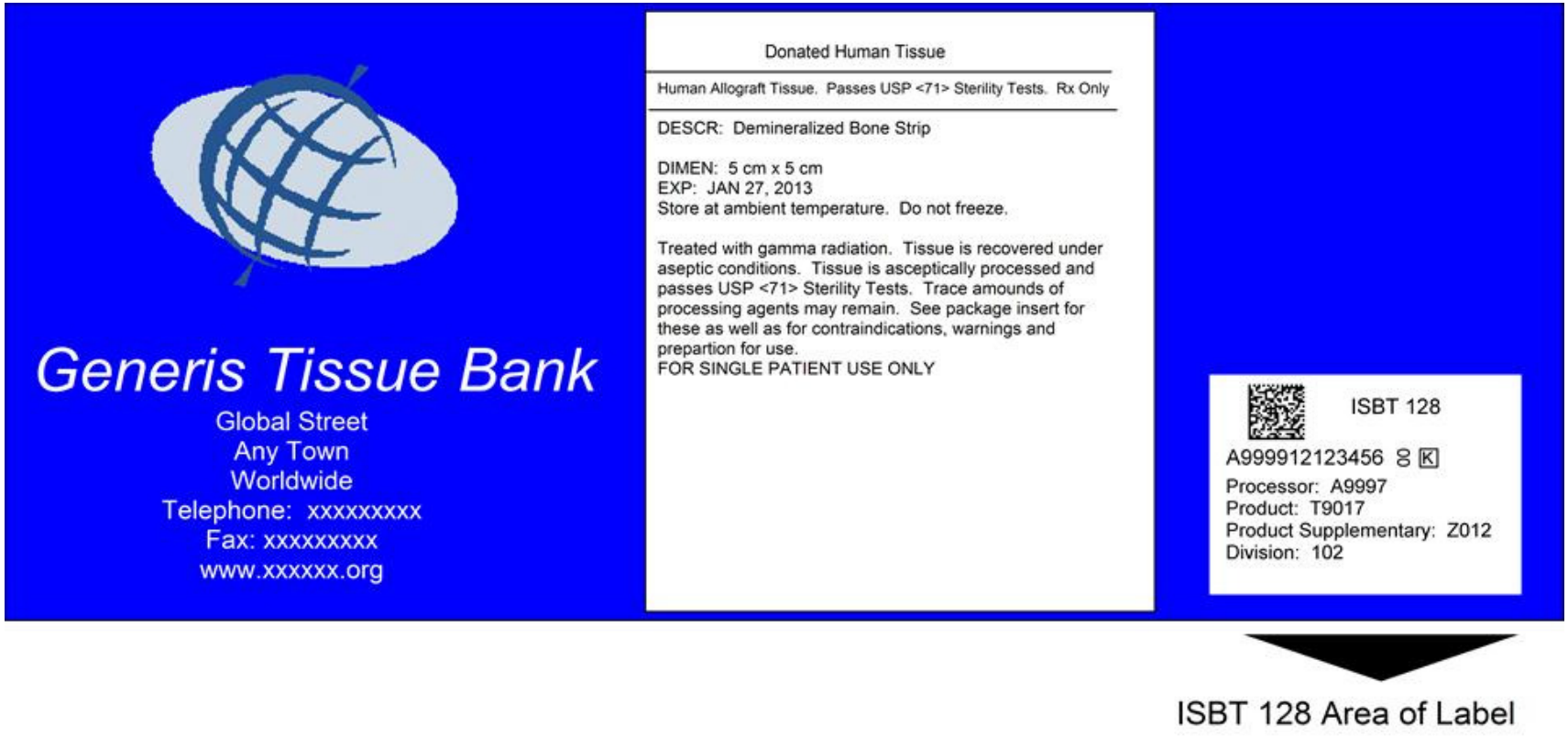
ENDOPATH®

dextrus™

Finger-Mounted
Locking Forceps

REF	FMF02

UDI Application Example



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 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

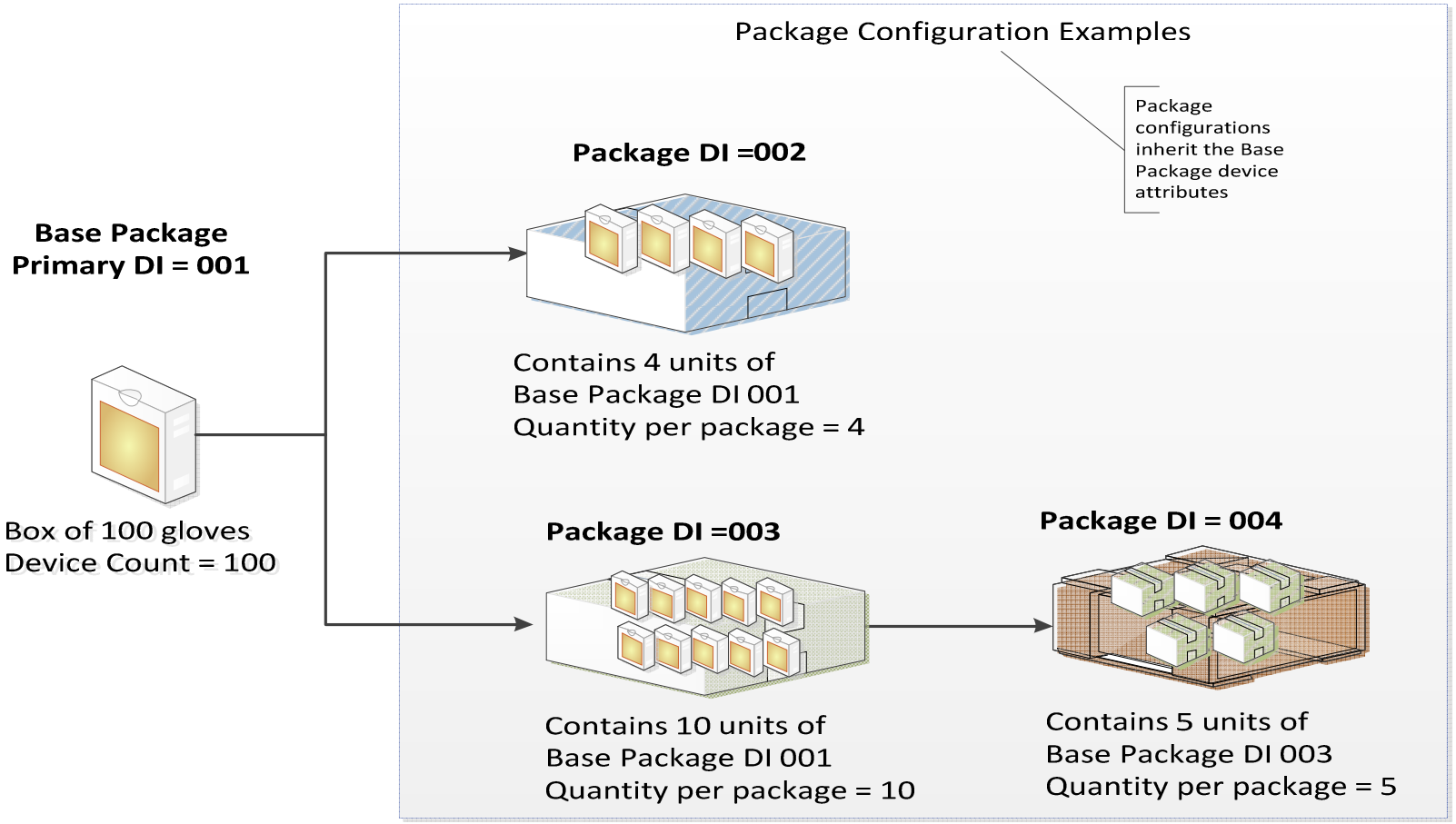
3rd – Global UDI Database

For Each Device Identifier:

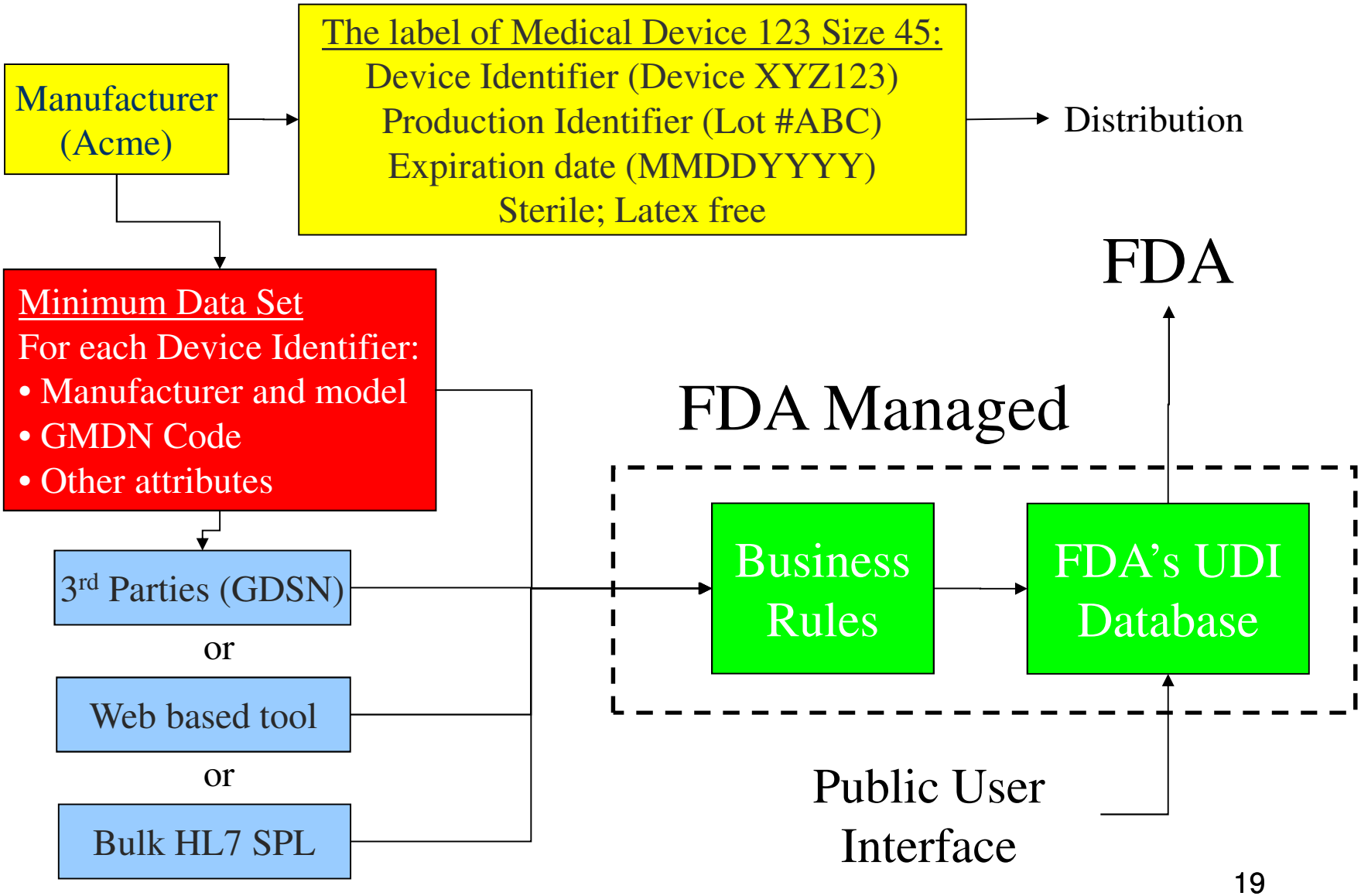
- Labeler (DUNS), Make/model; Brand/Trade Name
- Clinically relevant size
- Device version/model number
- Catalogue/reference number
- Controlled by – Lot and/or Serial Number; Exp. Date
- GMDN and procode terms
- Whether packaged sterile
- Contains latex
- FDA premarket authorization; Listing number
- For single-use; Kit, Combo Product
- Higher levels packaging

3rd – Global UDI Database

Unique Device Identification Database (UDID) – Package Illustration



FDA's Global UDI Database



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