# FDA's Unique Device Identification (UDI) System

Jay Crowley
Senior Advisor for Patient Safety
Food and Drug Administration
jay.crowley@fda.hhs.gov
301-796-5995

# 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.

# 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

1. Combination of 4 distinct steps:
2. Develop a standardized system to develop the unique device identifiers (UDI)
3. Place the UDI in human readable and/or AutoID on a device, its label, or both
4. Create and maintain the UDI Database
5. Adoption and Implementation

- Develop UDI code according to ISO 15459 [issuing agencies like 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

# General Exemptions (1/2)

- Class I devices are not required to have production identifiers in UDI
- Devices, other than prescription devices, made available for purchase at a retail establishments.
- 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

# General Exemptions (2/2)

- Devices used for research, teaching, or chemical analysis, and not intended for any clinical use
- Custom devices within the meaning of 812.3(b)
- Investigational devices (part 812)
- Veterinary devices not intended for human use
- Devices intended for export from the US
- Device held by the Strategic National Stockpile
- Devices which FDA has established a performance standard and has included an UDI exception
- Shipping containers

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

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

℞ Only

0-45

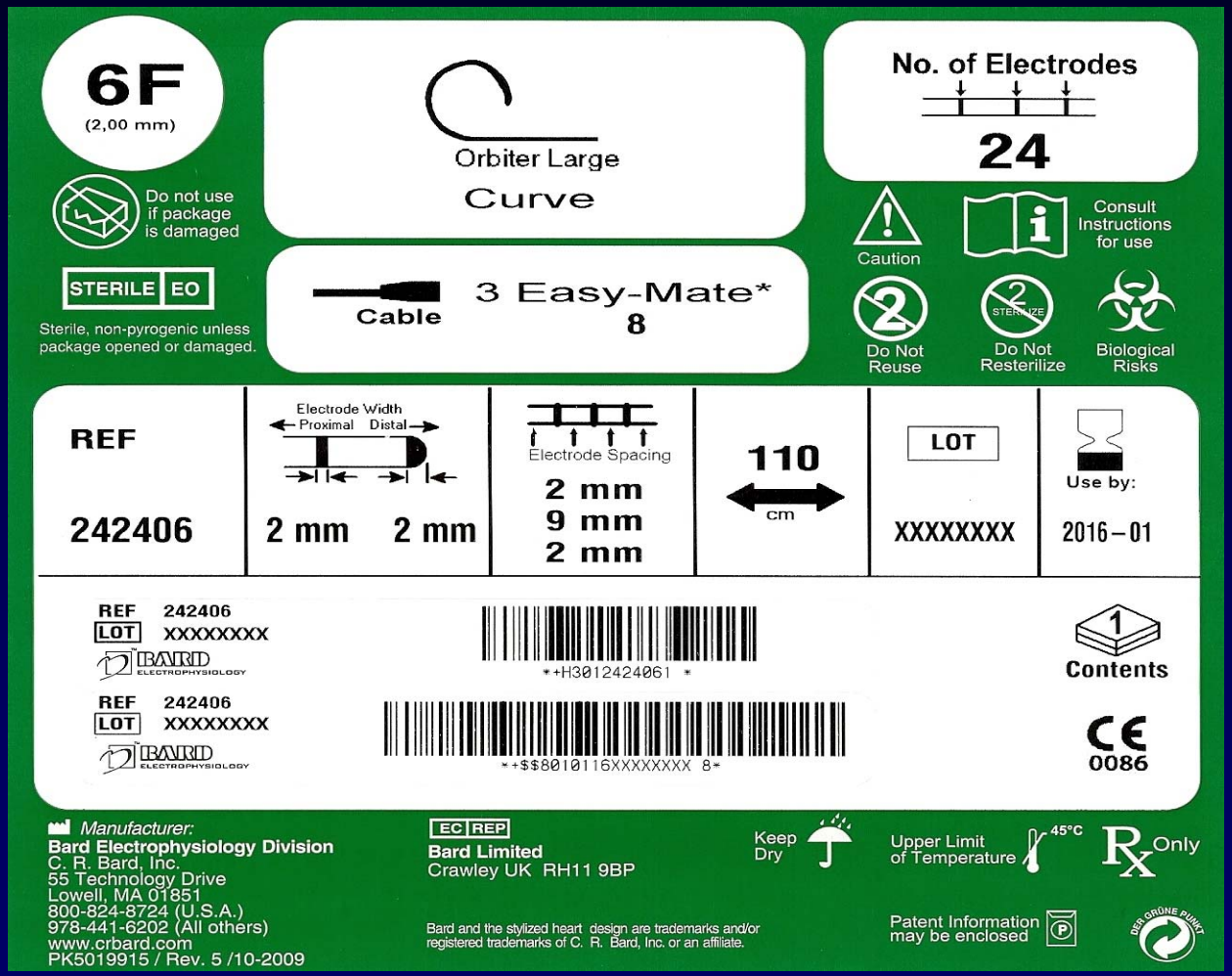
D150PPLB02 Rev.D

ENDOPATH®

dextrus™

Finger-Mounted Locking Forceps

| REF | FMF02 |
|---|---|

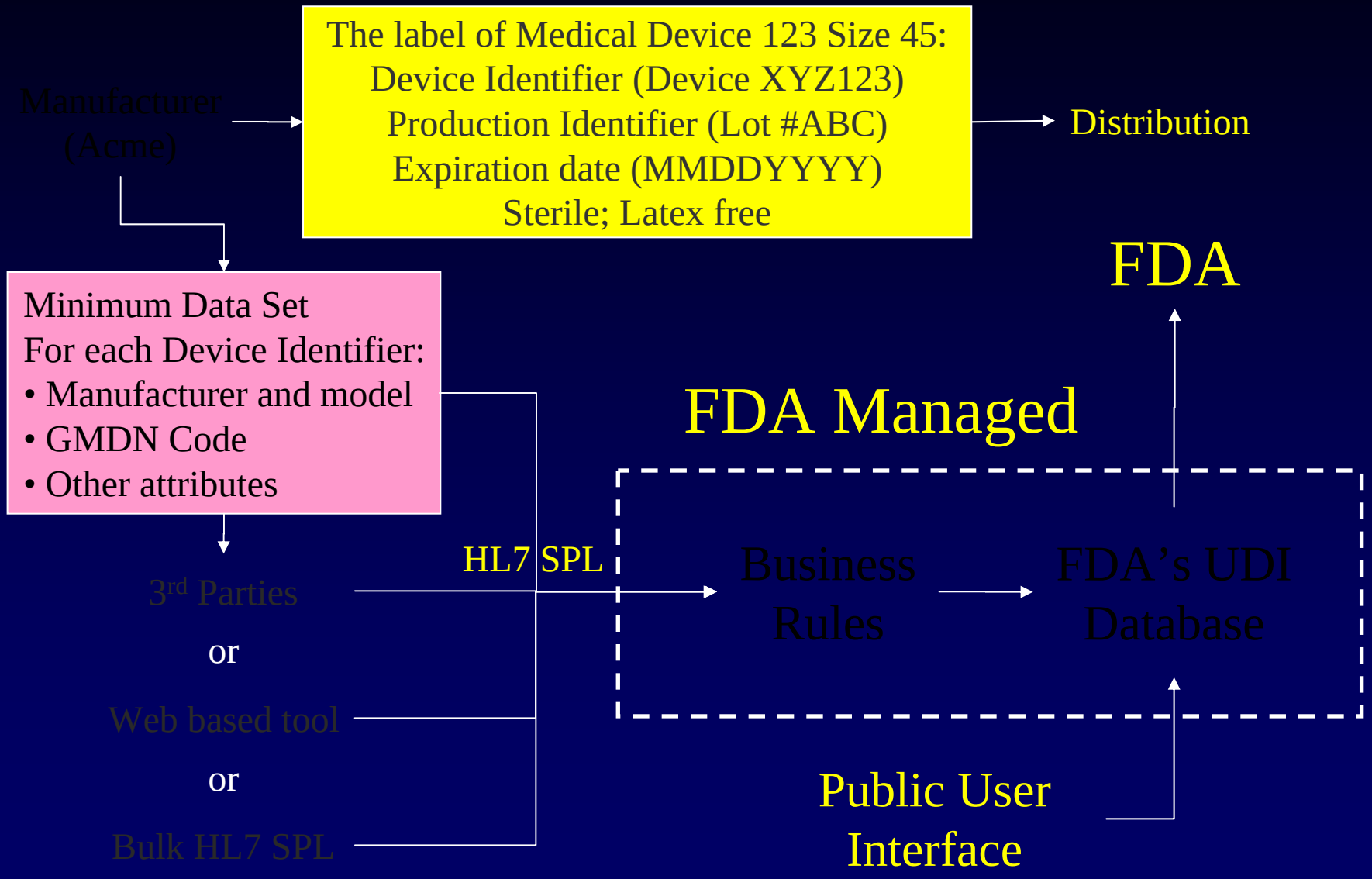

6F
(2,00 mm)
Orbiter Large
Curve
No. of Electrodes
24
Do not use if package is damaged
Caution
Consult Instructions for use
STERILE EO
Sterile, non-pyrogenic unless package opened or damaged.
Cable
3 Easy-Mate*
8
Do Not Reuse
Do Not Resterilize
Biological Risks
REF
242406
Electrode Width
Proximal Distal
2 mm 2 mm
Electrode Spacing
2 mm
9 mm
2 mm
110
cm
LOT
XXXXXXXX
Use by:
2016–01
REF 242406
LOT XXXXXXXX
BARD ELECTROPHYSIOLOGY
*+H3012424061 *
REF 242406
LOT XXXXXXXX
BARD ELECTROPHYSIOLOGY
*+$$8010116XXXXXXXX 8*
Contents
CE
0086
Manufacturer:
Bard Electrophysiology Division
C. R. Bard, Inc.
55 Technology Drive
Lowell, MA 01851
800-824-8724 (U.S.A.)
978-441-6202 (All others)
www.crbard.com
PK5019915 / Rev. 5 /10-2009
EC REP
Bard Limited
Crawley UK RH11 9BP
Keep Dry
Upper Limit of Temperature
45°C
Rx Only
Bard and the stylized heart design are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.
Patent Information may be enclosed
DER GRÜNE PUNKT

# Combination Products and Kits

- Like other devices – intended to facilitate identification:
- 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 of the use of 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


Manufacturer (Acme)
The label of Medical Device 123 Size 45:
Device Identifier (Device XYZ123)
Production Identifier (Lot #ABC)
Expiration date (MMDDYYYY)
Sterile; Latex free
Distribution
FDA
Minimum Data Set
For each Device Identifier:
• Manufacturer and model
• GMDN Code
• Other attributes
FDA Managed
HL7 SPL
3rd Parties
or
Web based tool
or
Bulk HL7 SPL
Business Rules
FDA's UDI Database
Public User Interface

# 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)
- Direct part marking requirements are effective 2 years after class effective date

- Phase out national numbering system (NDC/NHRIC)

- Submit comments electronic or written comments on the proposed rule by **[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

- You may submit comments, identified by Docket No. FDA-2011-N-0090 and/or RIN No. 0910-AG31, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) at FAX: 202-395-7285, or e-mail comments to OIRA_submission@omb.eop.gov.

- Please mark your comments to the attention of the FDA desk officer and reference this rule.

# What's Next?

- FDA will consider all comments submitted.
- Final Rule – Coming Soon
- Implementation
- Training Stakeholders (Industry & Healthcare Professionals)

- www.fda.gov/UDI
- dsmica@fda.hhs.gov or 1-800-638-2041
- cdrhudi@fda.hhs.gov