

# Unique Device Identification: Unambiguous, Standardized and Harmonized

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# 2011- Year of the Rabbit

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- Metal Rabbit - Calm and gentle, but persistent.
- One of the most cautious signs in the Chinese zodiac – they are the chess players who take their sweet time before making a move.
- Famous Rabbits include: Albert Einstein, Leon Trotsky, Frank Sinatra, Pope Benedict XVI, Angelina Jolie, Brad Pitt, Johnny Depp, David Beckham, Tiger Woods, Whitney Houston.

# 2011- Year of the Device

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- UDI Development – slow, thoughtful, thorough
- Devices cover a very wide range of medical products – from the simplest to the most complicated
- Needs to be flexible, adaptable, and scaleable
- Includes other issues such as GMDN, HL7 SPL, development of UDID
- Information associated with the device in the UDID is critical to safe distribution and use

# Current Device Identification

- Non-standard device identification systems; standards used in different ways
- Not necessary unique or unambiguous
- Does not include all necessary levels of uniqueness
- Manufacturers' own number/catalogue number
- Distributors' – apply different, proprietary number; lot or serial number not captured
- Hospital – yet different identification number/code
  - Information on use not usually captured
  - Control numbers rarely captured

# Future Device Identification

Develop a system to identify medical devices, which 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**

# UDI brings... Global Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion (location systems)
- Comparative effectiveness (e.g., registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative - strengthening FDA's ability to query data systems for relevant device information

# 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.

# GHTF UDI ADWG

- Formed October 2008
- EC Chair (Laurent Selles)
- Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA), Japan, Canada
- AHWP recently joined (China)
- Washington April 2010; Brussels June 2010; Ottawa September 2010; May 2011
- Guidance submitted to Nov 2010 SC meeting
- Public Document – available at:  
<http://www.gh tf .org/ahwg/ahwg-proposed.html>  
Comments due by 30 April 2011.



# Establishing a UDI System

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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

# 1<sup>st</sup> – 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

## 2<sup>nd</sup> – 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 (label) – not requiring serialization.
- 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 Example

ENDOPATH®  
**dextrus**

Finger-Mounted  
 Locking Forceps

REF FMF02      LOT 1Q34

080100      QTY 4



(01) 2 081019001 002 4



(17)080100(10)1Q34



**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 R

Rx Only



D 150P L B02 Rev.D

ENDOPATH®  
**dextrus**

Finger-Mounted  
 Locking Forceps



REF FMF02



# UDI Application Example

 **Medtronic**

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05504SP

Catheter Connecting Cable, 4 Conductor  
Câble de connexion de cathéter, 4 Conducteurs  
Katheteranschlußkabel, 4 Pol  
Cable de conexión de catéter, 4 Conductores  
Cavo di collegamento per cateteri, 4 Pini  
Kabel voor catheterverbinding, 4 - pins geleider  
Forbindelseskabel for kateter, 4 ledere  
Kabel för kateteranslutning, 4 ledare  
Cabo de ligação do cateter, 4 condutores  
Καλώδιο σύνδεσης καθετήρα, 4κλωνο

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 <b>LOT</b> H612 Lot Number	 122 cm (4 ft) Length	 <b>STERILE R</b> Sterilized using irradiation
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 <b>2009-01-15</b> (YYYY-MM-DD) Use By	 Attention. See accompanying documents.
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 <b>2007-01-15</b> (YYYY-MM-DD) Manufacturing Date
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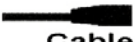





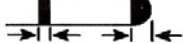

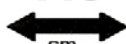











(01)00681490024464(17)090115(10)H612 PIN: 082104004

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Manufactured for: Medtronic, Inc. Minneapolis, MN 55432 USA	 <b>USA</b> Rx only		
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# UDI Application Example

<p><b>6F</b> (2,00 mm)</p>	 <p>Orbiter Large Curve</p>	<p>No. of Electrodes</p>  <p><b>24</b></p>			
 <p>Do not use if package is damaged</p>	 <p><b>3 Easy-Mate*</b> <b>8</b></p>	 <p>Caution</p>  <p>Consult Instructions for use</p>  <p>Do Not Reuse</p>  <p>Do Not Resterilize</p>  <p>Biological Risks</p>			
<p><b>STERILE EO</b></p> <p>Sterile, non-pyrogenic unless package opened or damaged.</p>					
<p><b>REF</b></p> <p><b>242406</b></p>	<p>Electrode Width ← Proximal Distal →</p>  <p><b>2 mm 2 mm</b></p>	<p>Electrode Spacing</p>  <p><b>2 mm 9 mm 2 mm</b></p>	<p><b>110</b></p>  <p>cm</p>	<p><b>LOT</b></p> <p>XXXXXXXXXX</p>	<p>Use by:</p> <p>2016-01</p>
<p><b>REF</b> 242406 <b>LOT</b> XXXXXXXX</p> 	 <p>*H3012424061*</p>		 <p><b>1</b> Contents</p>		
<p><b>REF</b> 242406 <b>LOT</b> XXXXXXXX</p> 	 <p>*S\$8010116XXXXXXXX 8*</p>		<p><b>CE</b> <b>0086</b></p>		
<p><b>Manufacturer:</b> Bard Electrophysiology Division C. R. Bard, Inc. 55 Technology Drive Lowell, MA 01851 800-824-8724 (U.S.A.) 978-441-8202 (All others) www.crbard.com PK5019915 / Rev. 5 / 10-2009</p>	<p><b>EC REP</b> Bard Limited Crawley UK RH11 9BP</p>	<p>Keep Dry</p> 	<p>Upper Limit of Temperature <math>45^{\circ}\text{C}</math>  <b>Rx Only</b></p>		
<p>Bard and the stylized heart design are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.</p>		<p>Patent Information may be enclosed </p>			

# Combination Products and Kits

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Like other devices – intended to facilitate identification:

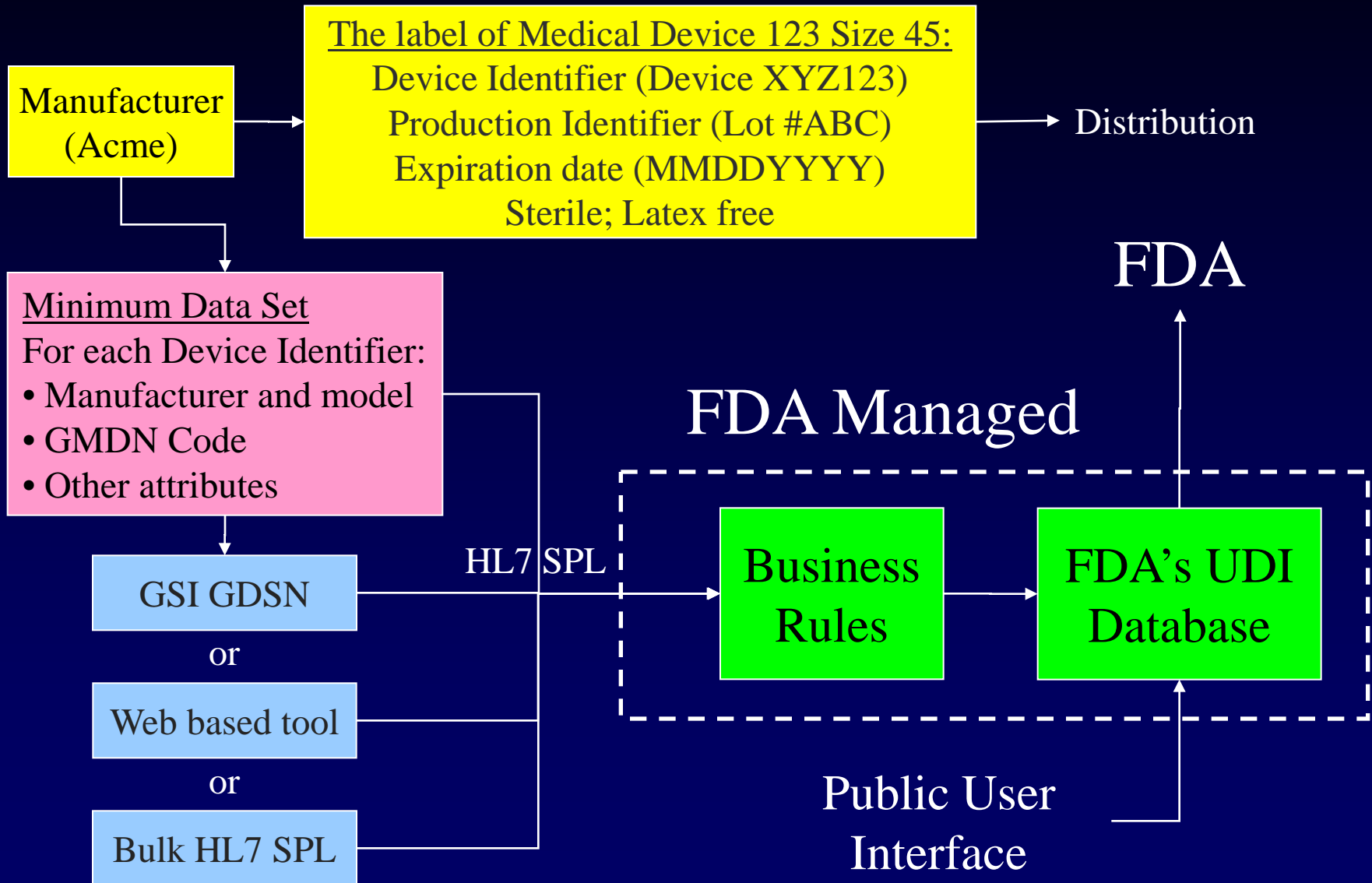
- Combination product (device) has its own UDI; each device should have its own UDI.
- Each kit (devices only) has its own UDI; each device in a kit should also have its own UDI.



## 3<sup>rd</sup> – Global UDI Database

- 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)
- FDA premarket authorization (510k, PMA)
- **FDA Listing Number**

# FDA's UDI Database



# Implementation

- Based on premarket risk class:
  - class III – 12 months after final rule
  - class II – 36 months after final rule
  - class I – 60 months after final rule
- Allows stakeholders to jointly learn and for mid-course corrections
- Phase out national numbering system (NDC/NHRIC)
- Robust alternate placement and exception process
- Expect manufacturers and groups of manufacturers to submit requests – results of which will posted.

# 4<sup>th</sup> – Adoption and Implementation

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- Facilitate distributor uptake and use
- Facilitate hospital uptake and use
- Facilitate use of UDI throughout device lifecycle
- Drive integration – MMIS-Clinical
- Drive appropriate use of UDI in EHRs – and use of EHRs for registries and other postmarket activities

# HL7 SPL

- HL7 SPL r5 models UDI GHTF data elements
- Definitions
- Representation of Various Product combinations
- Identifying a Product without packaging
- Defining System requirements for UDID and internal FDA Product Information Database
- Accept , Store and Transmit HL7 SPL message

# GMDN

- Development of global nomenclature to support regulatory and research activities.
- Preferred terms provide high degree of specificity
- Used for signal detection and device comparisons during data surveillance and analyses
- New governance model and activities in place
- Sustainable funding model under development
- Used with UDI/UDID to provide multiple levels of use (general → specific)

# Unique Device Identification

[www.fda.gov/MedicalDevices/  
DeviceRegulationandGuidance/  
UniqueDeviceIdentifiers](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers)

Email: [cdrhudi@fda.hhs.gov](mailto:cdrhudi@fda.hhs.gov)