

Unique Device Identification Update – FDA and GHTF

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

UDI Can Improve... 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

Medical Device Identification

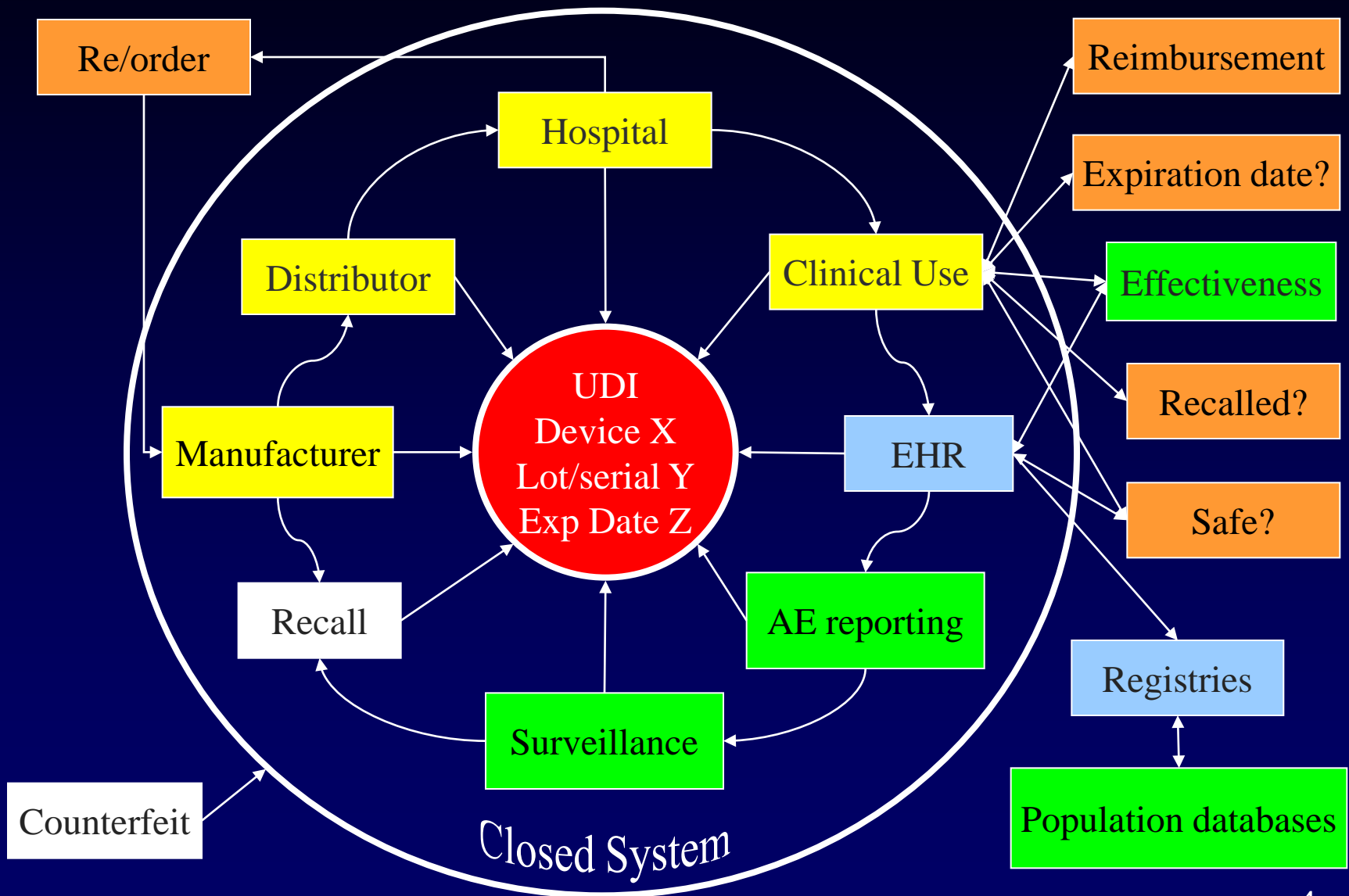
Develop a system to identify medical devices, which is:

- 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**

Future Information Lifecycle



Balanced Approach

Specific

- Tell me how and when
- Select a UDI standard
- Select an auto-ID standard
- Describe application for every device
- Implementation
- Require participation

Flexible

- Allow SSOs/stakeholders to develop best approach
- Based on UDI Standards
- UDI Placement
- Various AIDC standards
- Use on different devices
- Application/integration
- Data attributes

Medical Devices Include...

A very wide range of medical products – such as:

- Traditional hospital based devices (beds, ventilator)
- Implants
- In vitro diagnostic devices (IVDs) – both clinical lab and Point of Care (POC).
- Health Information Technology (HIT) – e.g., EHRs
- Stand-alone software
- Convenience kits
- Combination products
- Used in alternative sites – e.g., homecare, dental

GHTF UDI ADWG

- Formed October 2008
- EC Chair (Laurent Selles)
- Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA), Japan, Canada
- AHWP recently joined (China)
- Public Document – available at:
www.gh tf.org/documents/AHWG-PD1-N2R1.doc
- Washington April 2010; Brussels June 2010; Ottawa September 2010
- Final guidance submitted to Nov 2010 SC meeting
- 6 month comment period

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.

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]
- 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

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

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
- Direct Part Marking (DPM) for some devices
- No specific technology would be identified (technology neutral)
- Identify a series of standards (linear barcode, 2-dimensional barcode, RFID)

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**

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 Pins
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

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


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


Manufactured for: Medtronic, Inc. Minneapolis, MN 55432 USA			
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UDI Application Example

RX

2.5 12

RX



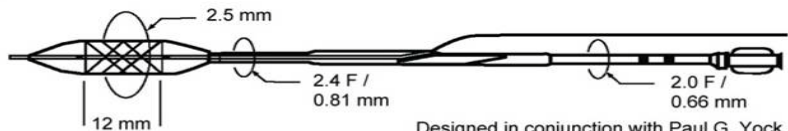
XIENCE V

2.5 12

RX

XIENCE V
Everolimus Eluting
Coronary Stent System


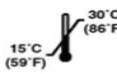


REF 1009527-08



Designed in conjunction with Paul G. Yock, M.D.

5 F / 0.056"
1.42 mm


RX

STERILE EO

LOT 8012201

S4544

ATM	kPa	
8 (NOM)	811	2.46 mm
9	912	2.52 mm
10	1013	2.58 mm
11	1115	2.63 mm
12	1216	2.68 mm
13	1317	2.72 mm
14	1419	2.75 mm
15	1520	2.78 mm
16 (RBP)	1621	2.81 mm
17	1723	2.84 mm
18	1824	2.87 mm

WPL2060859-01 (LABEL SAMPLE)

XIENCE V
2.5 mm x 12 mm


LOT 8012201

S4544
REF 1009527-12


RX

XIENCE V 2.5 mm x 12 mm

RX



(01) 0 8717648 06248 3






(17) 090213 (10) 8012201 (91) 7200

REF 1009527-12

LOT 8012201

 S4544

 2008-02-15  2009-02-13

 Abbott Vascular
Santa Clara, CA 95054-2807 USA
TEL: (800) 227-9902 FAX: (800) 601-8874
Outside USA TEL: (951) 914-4669
Outside USA FAX: (951) 914-2531

EC REP

Abbott Vascular International BVBA
1831 Diegem, BELGIUM
TEL: + 32 2 714 14 11 FAX: + 32 2 714 14 12

PPL2057757 (5/4/07)

UDI Application - DPM

Where feasible – DPM required for:

- Reusable/re-sterilized devices
- Long-term implants
- Stand-alone software

Manufacturers can decide not technologically feasible.

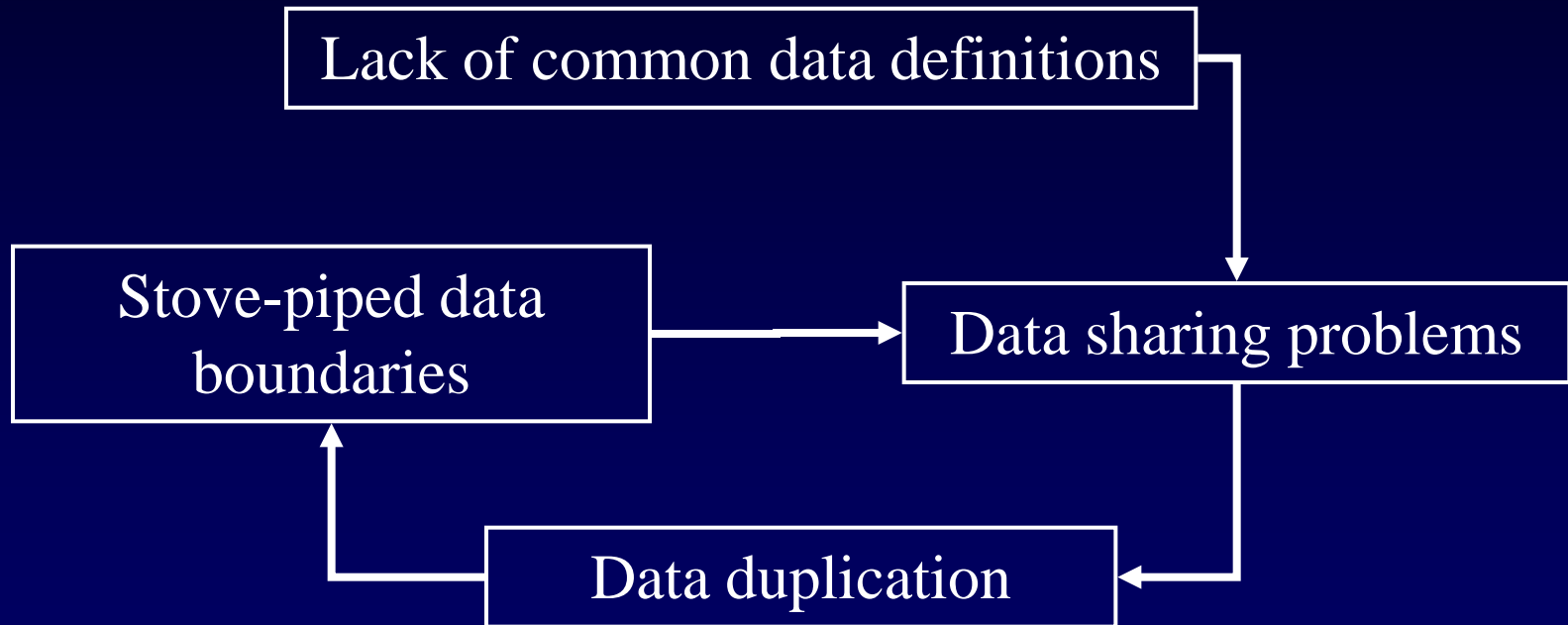
Combination Products and Kits

- Each combination product with device PMOA has its own UDI.
- Each kit (devices only) has its own UDI
- Each separable device constituent part of a combination product gets its own UDI.
- Each device in a kit gets its own UDI

3rd - UDI Database Development

- 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**

Focus on Master Data



Focus on Master Data

- Agreed to, standard critical business data that can be shared across systems.
- Virtual or actual integration
- Policies and procedures for creation, access, update, and management of central resource.
- Emphasis on data quality, integration, single version of the truth, data stewardship.
- MDM is complementary to data warehousing and business intelligence

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CE 0344

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 45242-2839 USA

ETHICON ENDO-SURGERY, INC.
 a Johnson & Johnson company

Do not use if package is open or damaged
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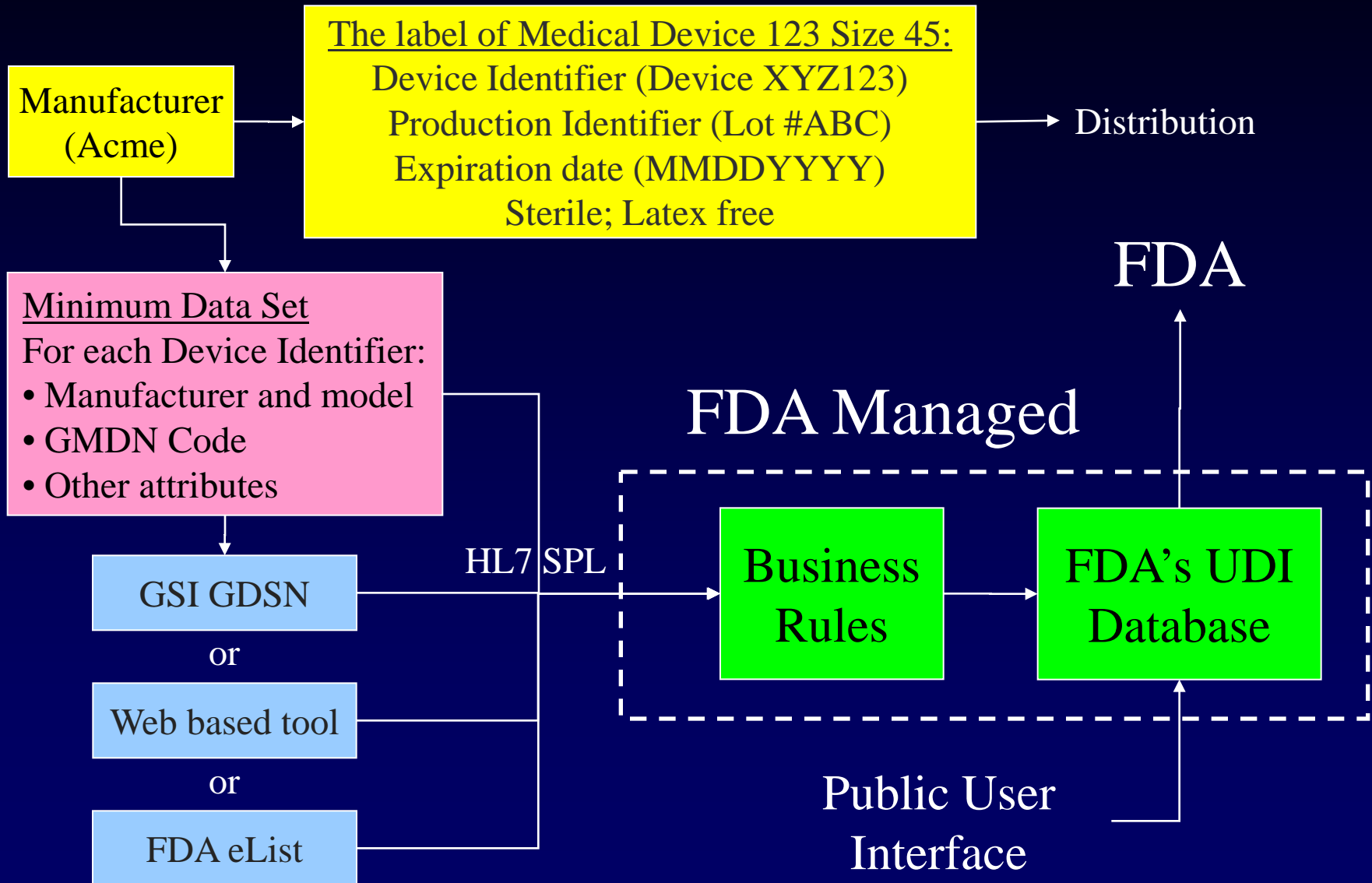
STERILE R **Rx Only** **1** **45**

REF FMF02

D150P1802 Rev D

- Device Identifier: GS1 2081090010024
- Endopath Dextrus Finger Mounting Locking Forceps
- Ethicon Endo-Surgery Inc, Cincinnati, Ohio
- Jane Smith; 1-888-888-8888; JSmith@JNJ.com
- Controlled by Lot; Expiration Date
- Packaged sterile; Single Use; Prescription
- GMDN code: 12345; 510k: K982013
- Package of 1; Storage conditions: between 0-24° C
- Does not contain latex or PVC

FDA's UDI Database



Business Rules for UDID

- Identify base packaging
- Validate that all of the DIs are unique
- Validate that all required fields are appropriately complete
- Check that the listing number is valid
- If changes to any attribute, require new DI
- Check for appropriate groupings of higher-levels of packaging

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.

HL7 SPL

- Working with HL7 SPL r5 Team to model 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)

4th – Adoption and Implementation

- 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

Limitations of UDI and UDID

- UDI is a foundational element – it unambiguously identifies a specific device (at its unit of use).
- Benefits accrue only if used by all stakeholders.
- UDID contains only “static” identifying and product information.
- UDID does NOT contain production information, such as lot or serial numbers – and is NOT track/trace or other similar purposes requiring the full UDI.
- UDID provides link to product information- not a replacement for Recalls/Adverse Event Databases.

Unique Device Identification

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

Email: cdrhudi@fda.hhs.gov