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)

The Development of FDA's Unique Device Identification System

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National Drug Code (NDC)

- Developed to identify drugs for reimbursement
- Identifies the manufacturer, product and package size
- FDA took over in 1972 (The Drug Listing Act)
- Pharmaceutical barcode rule – NDC in linear barcode
- Ubiquitous use has facilitated…
  - Analysis of claims in a large database
  - Retrospective chart review
  - Drug interaction checking and decision support
  - Identifying inappropriate prescribing and dispensing
  - Avoiding confusion with look/sound-alike drugs
  - Reporting adverse events

Limitations of the NDC

- US only system – each country/regulator has own
- Limited use for global supply chain applications
- Does not currently capture lot/serial numbers or expiration dates
- No rules for assigning identifiers to higher levels of packaging
- No rules for assigning identifiers to unit of use
- Requires/limits AIDC to linear barcode
- No national/global catalogue of all NDC numbers

Qualities of a UDI System

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**

Public Health Benefits

UDID provides global visibility and supports:

- Medical device recalls
- Adverse event reporting
- Tracking and tracing
- Supply chain security
- Anti-counterfeiting/diversion
- Disaster/terror preparation
- Shortages/substitutions
- Reduction of medical errors (e.g., bedside scanning)
- An easily accessible source of device information for patients and clinicians

UDI can also support…

- Device identification in registries
- Comparative effectiveness
- Documenting medical device use in patient's EHR/PHR, hospital information systems, and claims data
- Sentinel Initiative and other postmarket surveillance activities

- FDA Public Workshop on the Use of UDI for Postmarket Surveillance and Compliance – see www.fda.gov/udi

Benefits to Industry

- Facilitate marketing clearance for new indications
- Help purchasers to identify, order, and receive the correct device
- Facilitate visibility of their products throughout the supply chain and improve logistics
- Allow stakeholders to use the manufacturer's identifier
- Improve the efficiency/effectiveness of voluntary recall
- Help to identify counterfeit or diverted devices
- Facilitate importation activities
- Allow manufacturers to use a single UDI to meet global regulatory requirements

Benefits to FDA

- Better data on actual product performance when used as standard of care
- Improving FDA's use and understanding of adverse event reports
- Helping FDA to better understand the risk profile of particular devices
- Allowing FDA to mine population-based data sets to better understand the risks and benefits of device use within certain patient populations and indications
- In turn, this will allow FDA to better and more quickly address new concerns raised in premarket submissions

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 – and AHWP
- Washington April 2010; Brussels June 2010; Ottawa September 2010; May 2011
- Draft Guidance submitted to Nov 2010 SC meeting; released for public comments
- Final guidance approved September 2011
- At http://www.ghtf.org/ahwg/ahwg-final.html

Global Harmonization

A globally harmonized approach to UDI can:

- Allow device manufacturers to apply and use a single UDI across a wide array of regulators
- Provide a foundation for a global, secure supply chain
- Facilitate global visibility/track and trace
- Allow for automated import review
- Facilitate global efforts to address counterfeiting and diversion
- Support DoD, WHO and other efforts requiring global device identification

The Road to the Proposed Rule

The development consists of a number of steps:

1. Development of regulatory text (the legal language)
2. Development of preamble (the how and why)
3. Development of economic impact analysis
4. Approval by CDRH, FDA and then HHS
5. Approval by the Office of Management and Budget
6. Publication of proposed rule…

And then the Final Rule

And then the fun begins…

1. 90 day comment period
2. Possible public meetings
3. Review and analysis of comments
4. Response to comments
5. Development of final rule (with responses)
6. Then complete review again
7. And finally publication of the final rule

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

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
- 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

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

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a Johnson & Johnson company

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Do not use if package is open or damaged

Single patient use only

Does not contain latex or PVC

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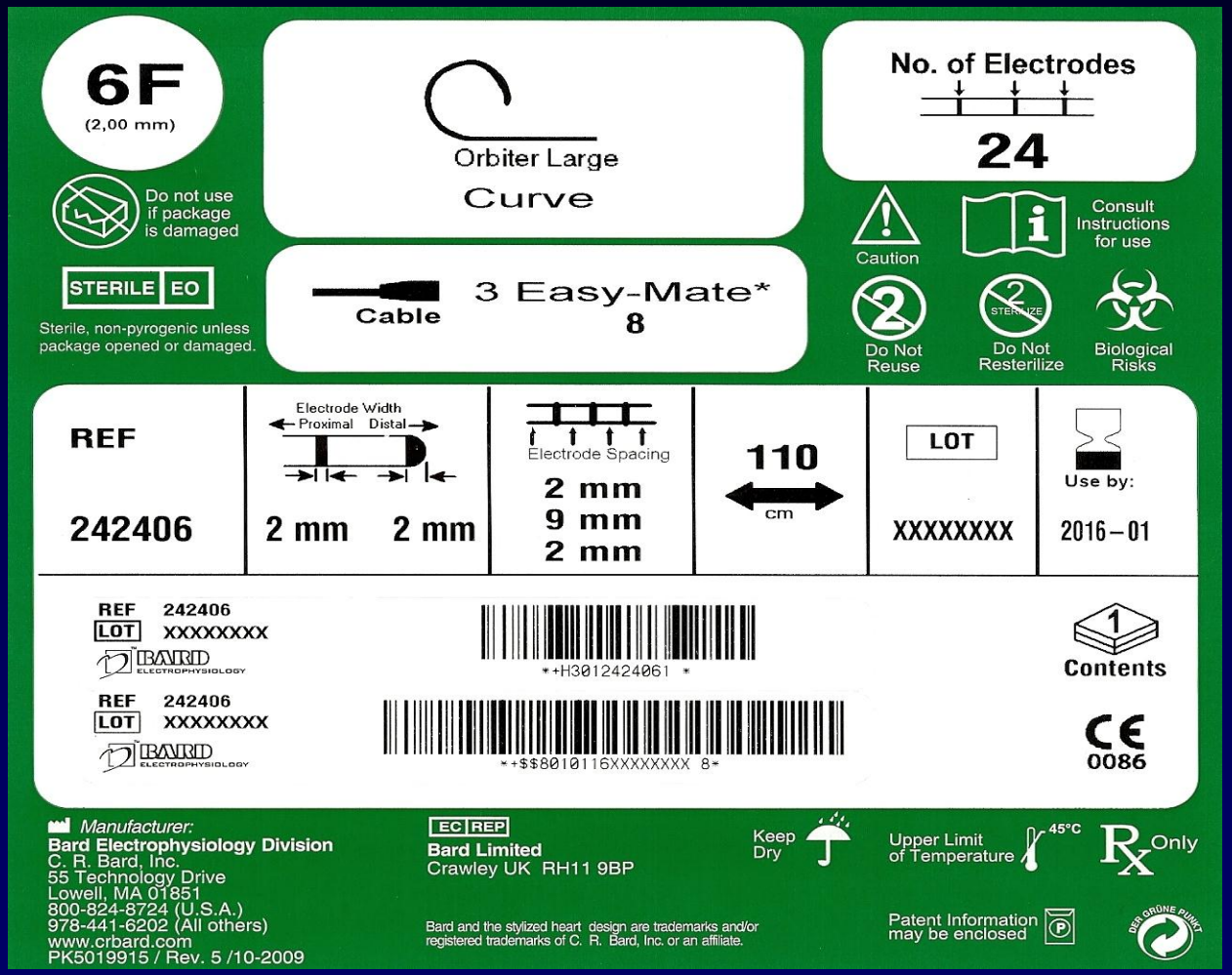
D150PPLB02 Rev.D

ENDOPATH®
dextrus™
Finger-Mounted
Locking Forceps

REF	FMF02

UDI Application Example



Combination Products and Kits

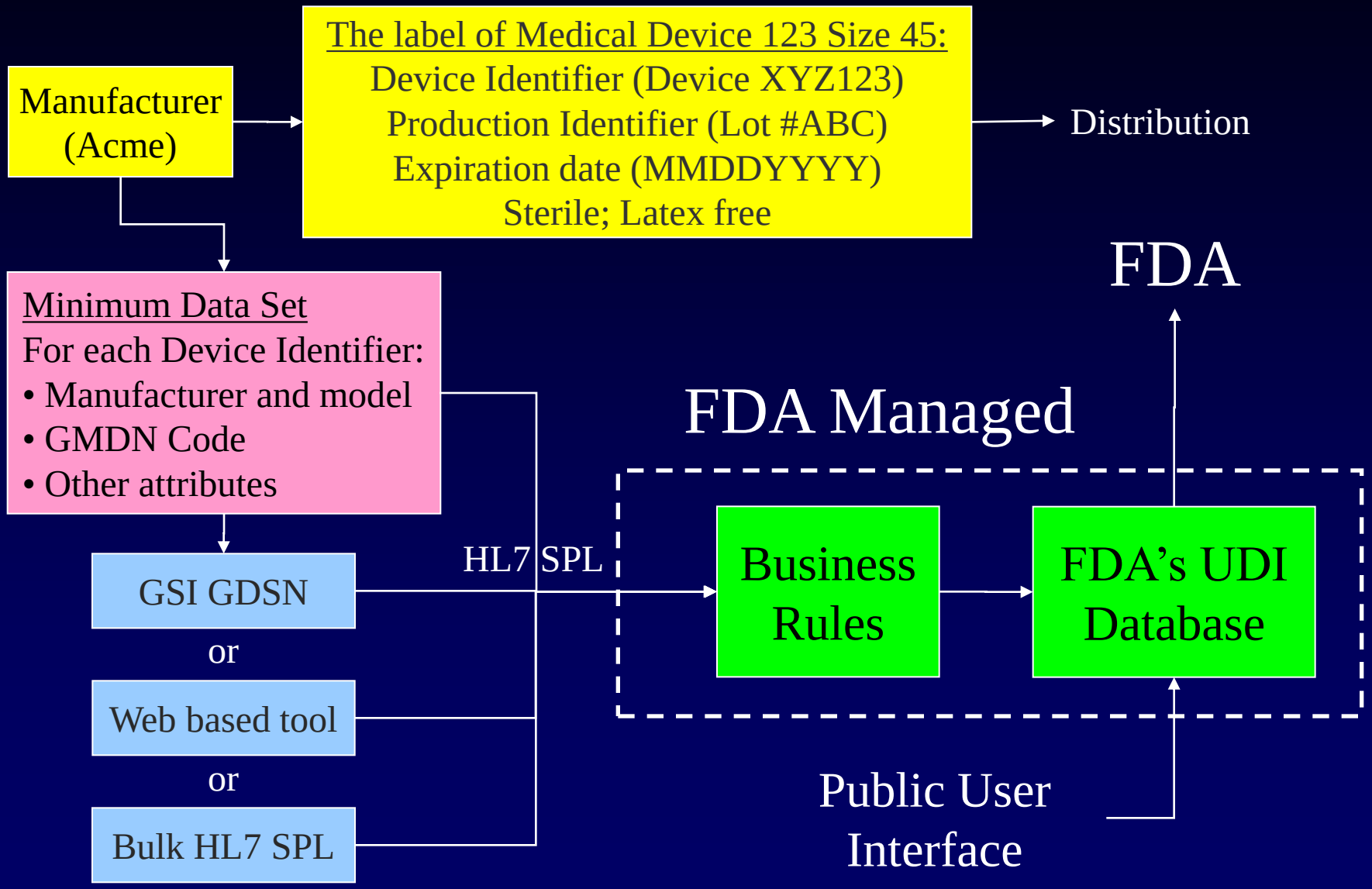
Like other devices – intended to facilitate identification:

- 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.

3rd – 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's UDI Database



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)
- Allows stakeholders to jointly learn and for mid-course corrections
- Phase out national numbering system (NDC/NHRIC)
- Robust alternate placement and exception process

Unique Device Identification

www.fda.gov/UDI

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