Unique Device Identification Update

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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

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

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**

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.

UDI Public Workshop

12 February 09 - 300 people attended; 4000 webcast

4 Panels addressed issues related to:

- Developing standardized UDIs
- Placing the UDI in human readable and/or AutoID on a device, its label, or both
- Creating and maintaining the UDI Database
- Promoting adoption and implementation

Received 60 written comments.

GHTF UDI ADWG

- Formed October 2008
- EC Chair (Laurent Selles)
- Members US (FDA, AdvaMed), Europe (EC, Eucomed, EDMA, Matthias Neumann), Japan (Hiroshi Ishikawa)
- AHWP recently joined
- Public Document out for comment – comments due 30 March 2010. Available at: www.ghtf.org/documents/AHWG-PD1-N2R1.doc

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

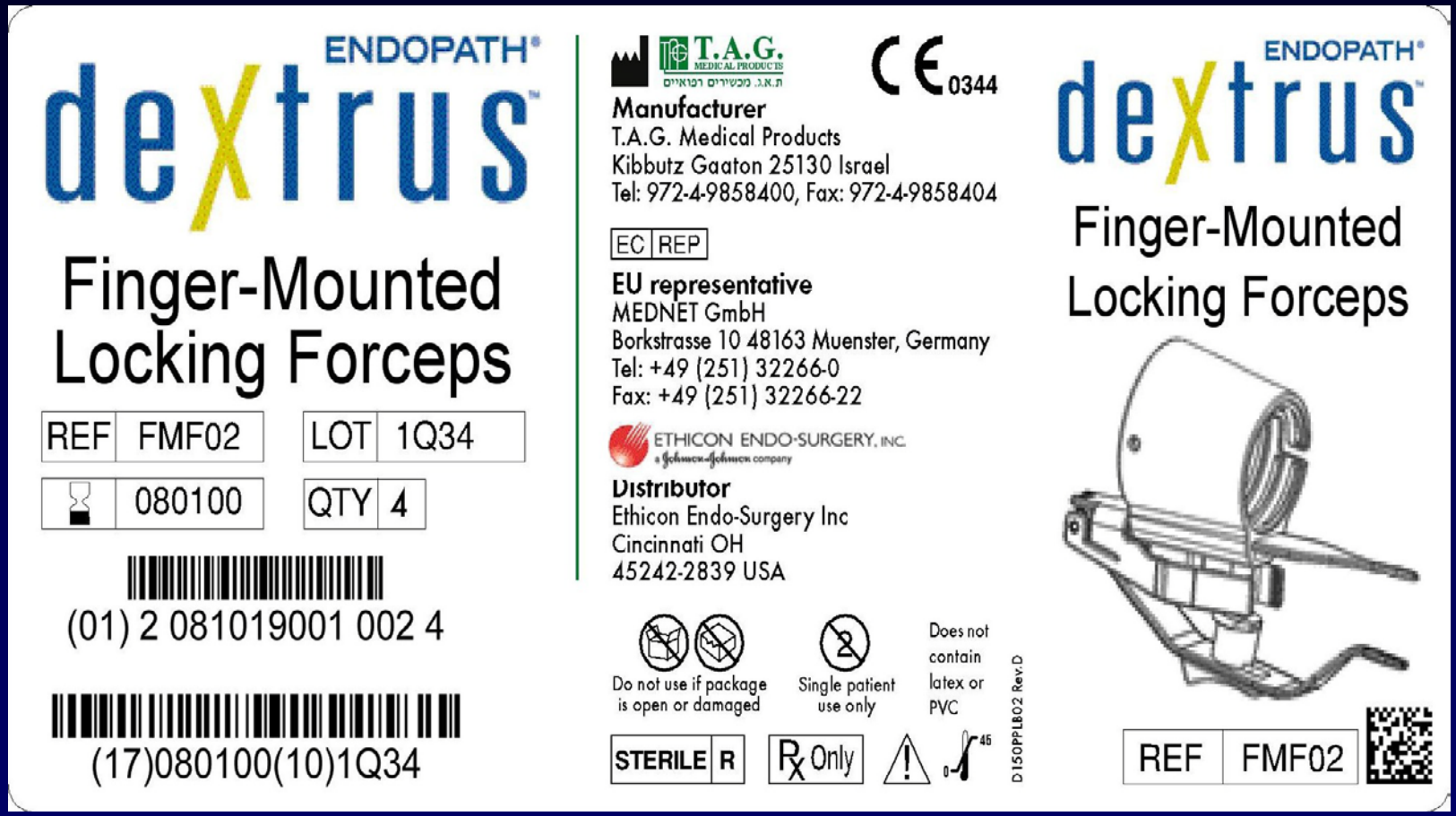
1st – Developing the UDI

- 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] if currently serialized – serial number; if currently identified at the lot, the lot number, and expiration date
- Risk based approach – DI; DI + lot; DI + serial (or lot and serial)

2nd – UDI Application

- Applied at all levels of packaging, down to the lowest level (the patient use level or 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)

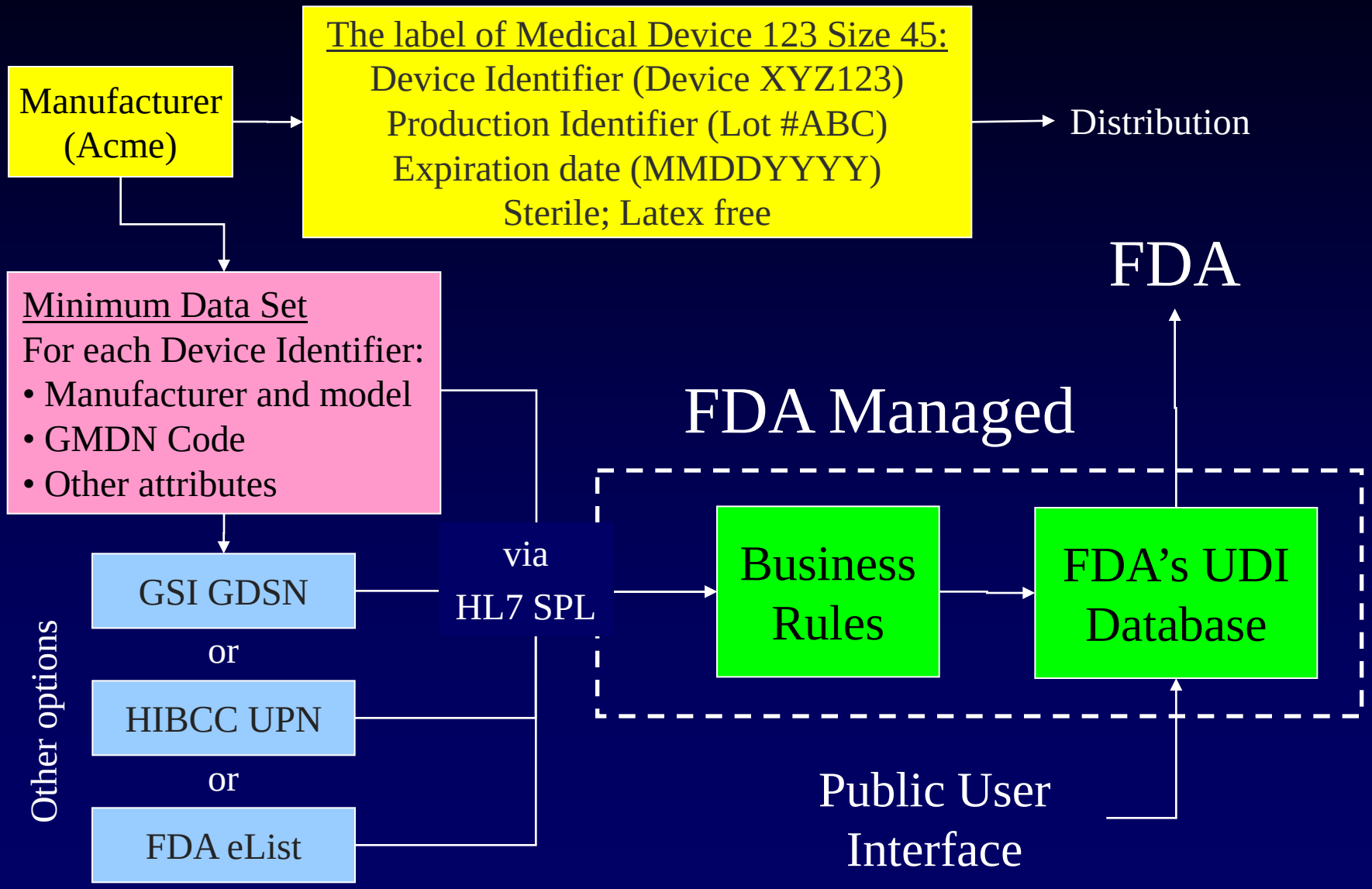
UDI Application Example

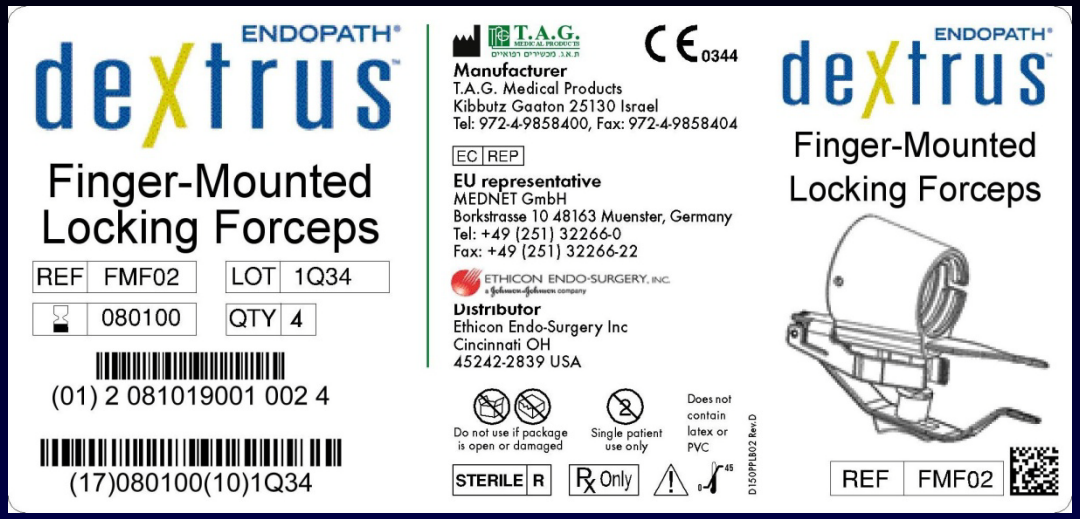


3rd - UDI Database Development

- Device Identifier Type/Code [GTIN, HIBCC]
- Make/model; Brand/Trade Name; Description
- Device model number (or reference number)
- Size; Unit of Measure/Packaging level/quantity
- Control – Lot and/or Serial Number; Exp. Date
- Contact name, phone, email
- GMDN Classification code/term
- Storage condition; Single Use; Sterility; Restricted Use
- Contains known, labeled allergen (e.g., latex)
- URL for additional information – Web address
- Special Instruction for use

FDA's UDI Database





- Device Identifier: GS1 20810900100024
- 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; Manufactured in Israel
- Package of 1; Storage conditions: between 0-24º C
- Does not contain latex or PVC

UDI Database Pilot

- Purpose: Assess the feasibility of collecting, storing, and retrieving UDI data from initial creation (manufacturer) to point of use (hospital) .

Results:

- Data suppliers (manufacturers) had concerns about data definitions, obtaining the data from various sources and manipulating for UDI upload.
- Participants confused about the purpose/use of UDID.
- Users (hospitals) liked UDID – it provided data they regularly need - e.g. information related to recalls and identifying alternate products/manufacturers for recalls.

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” information.
- Includes identifying information and other attributes about the device.
- UDID does NOT contain production information, such as lot or serial numbers.
- UDID is NOT track/trace or other similar purposes requiring the full UDI
- UDID provides link to Better Product Information- not a replacement for Recalls/Adverse Event Databases.

4th – Adoption and Implementation

- Resolve technology issues – barcodes, RFID, DPM
- Develop appropriate UDI Database
- Facilitate distributor uptake and use
- Facilitate hospital uptake and use
- Facilitate use of UDI throughout device lifecycle
- Develop medical error reduction (e.g., latex)
- Drive integration – MMIS-Clinical
- Drive appropriate use of UDI in EMRs
- Determine appropriate role in reimbursement
- Address privacy concerns

Unique Device Identification

www.fda.gov/MedicalDevices/
DeviceRegulationandGuidance/
UniqueDeviceIdentifiers

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