"In attempting to arrive at the truth, I have applied everywhere for information, but *in scarcely an instance have I been able to obtain hospital records fit for any purposes of comparison.*

If they could be obtained, …they would show how…money was being spent, what amount of good was really being done with it..; and… *these improved statistics would tell us more of the relative value of particular operations and modes of treatment* .. and the truth thus ascertained would enable us to save life and suffering, and to improve the treatment and management of the sick…"

Florence Nightingale
Notes on hospitals (1859, revised 1863)

FDA CDRH UDI Update
Medical Device Interoperability Workshop

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Update

- UDI
  - Authority and Goals of UDI Project
  - Establishment of UDI
  - Database Issues
  - Implementation Issues
- Event Problem and Evaluation Code Vocabulary

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.

HR 3962 – Health Care Reform

SEC. 2571. NATIONAL MEDICAL DEVICE REGISTRY

(b) Electronic Exchange and Use in Certified Electronic Health Records of Unique Device Identifiers-

…

(2) STANDARDS, IMPLEMENTATION CRITERIA, AND CERTIFICATION CRITERIA- The Secretary of Health and Human Services, acting through the head of the Office of the National Coordinator for Health Information Technology, *shall adopt standards, implementation specifications, and certification criteria for the* *electronic exchange and use in certified electronic health records of a unique device identifier for each covered device referred to in paragraph (1), if such an identifier is required by section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)) for the device.*

(c) *Unique Device Identification System- The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue proposed regulations to implement section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)) not later than 6 months after the date of the enactment of this Act.*

Current Device Identification

- **Non-standard device identification systems; standards used in different ways**
- **Not necessarily unique or unambiguous**
- ***Different numbers along the supply chain***
  - **Manufacturer - own number/catalogue number**
  - **Distributors – different, proprietary number; lot or serial number not captured**
  - **Hospital – different identification number/code**

Unique Device Identification Project

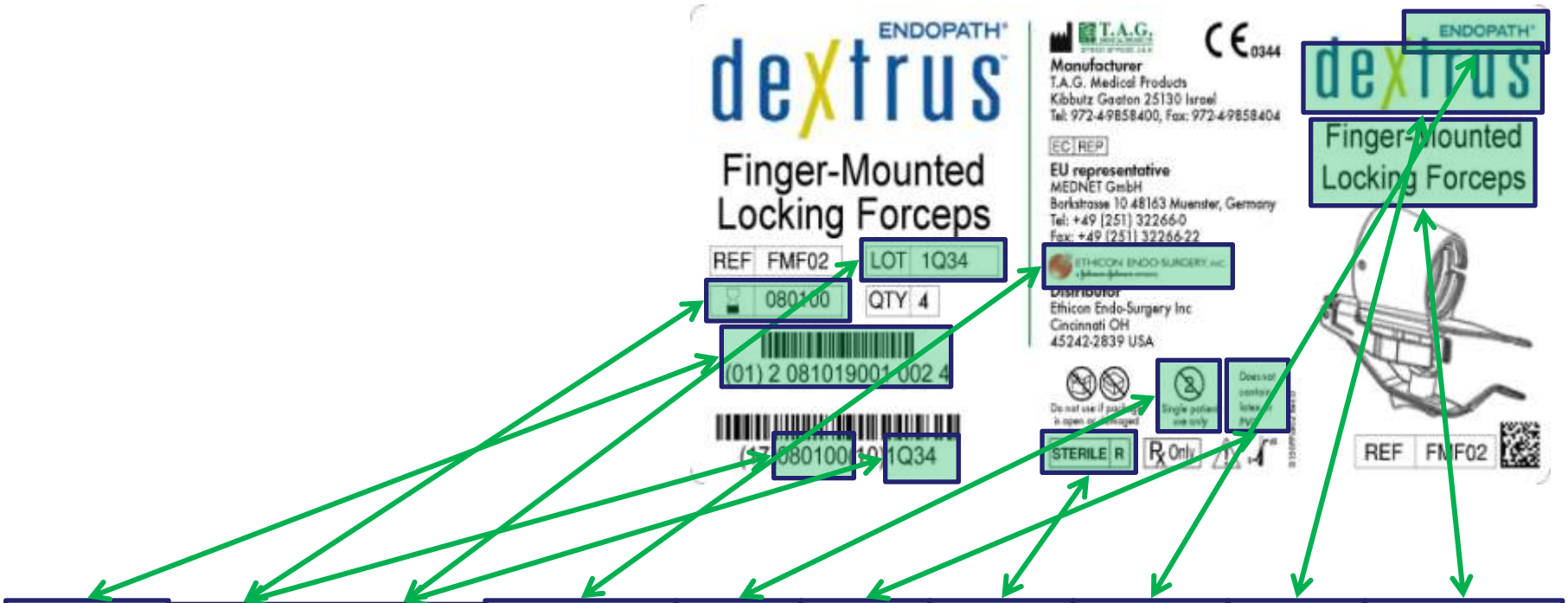
Goal: Develop a medical devices identification system that is:

- **Unambiguous**
- **Standardized**
- **Unique at all levels of packaging**
- **Harmonized internationally; and**
- **Facilitates the Storage, Exchange, and Integration of data**

Establishing a UDI System

1. Develop a standardized system to assign 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 – contains UDI + Associated Attributes (HL7 SPL for data exchange)
4. Promote Adoption and Implementation

2. UDI – Label and Submission
DRAFT EXAMPLE



UDI Code	Controlled by Exp. Date ? Y/N	Controlled by Lot # ? Y/N	Labeler	Single Patient Use? Y/N	Contains Latex? Y/N	Packaged as Sterile? Y/N	Brand Name	Trade Name	Common Device Name
(01) 2 081019001002 4	Yes 080100	Yes 1Q34	Ethicon Endo-Surgery Inc.	Yes	Yes	Yes	Endopath®	Dextrus	Finger-Mounted Locking Forceps

3. Create & Maintain UDI Database

GHTF Draft Attributes:

- Device Identifier Type/Code [GTIN, HIBCC]
- Unique Device Identifier
- Distributor/Labeler Information
- Product URL
- Product Information
  - Brand/Trade/Proprietary Name
  - Description
  - Device Type
    - GMDN code and term (or generic name)
- Model/Catalog/Reference #
- (Make and model)
- How Product Controlled (serial #, lot#, mfr date, exp date)
- Quantity and Packaging level (e.g., package of 3)

3. Create & Maintain UDI Database

Other GHTF Data Attributes:

- Storage condition (e.g., must be refrigerated)
- Reusability - Single Use (or limited number of reuses)
- Sterilization Status (e.g. packaged sterile, must be sterilized)
- Contains known, labeled allergen (e.g., latex)
- Marketing Information
  - Marketing status
  - Marketing dates

For more details - see GHTF Draft Discussion Paper:
http://ec.europa.eu/enterprise/newsroom/cf/document.cfm?action=display&doc_id=5556&userservice_id=1

UDI – Foundational Element

UDI will provide the foundation for:

- **more efficient and effective device recalls,**
- **improved postmarket surveillance,**
- **better adverse event reporting,**
- **better device identification in registries,**
- **ability to document specific device use in patient's Electronic Health Records,**
- **collection of device information in population-based data sets.**

BUT – only if UDI is captured, stored, integrated and exchanged by ALL stakeholders.

4. Adoption and Implementation

- Hospital uptake and use
- Integration with EMR and MMIS – HC Reform
- Integration with AE Reporting – UDI + Event Problem Codes/ISO 11073
- Relationship of UDI Code and ISO 11073
- Reimbursement CMS
- Distributor uptake and use
- Utility of UDID

Unique Device Identification

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentifiers

Email: cdrhudi@fda.hhs.gov

How can we help?

Event Problem Codes Project: What are they?

MedWatch 3500A – AE Reporting

5. Describe Event or Problem

An alarm sensor detected

…..

F. FOR USE BY USER FACILITY/IMPORTER *(Devices Only)*

10. **Event Problem Codes** *(Refer to coding manual)*

Patient Code		-		-	
Device Code	C63160	-	C49755	-	

Failure to Sense

Alarm

Event Codes: How assigned?

Filled out by Manufacturer when Healthcare provider leaves blank

- ***Device Problem*** **- device failures or problems encountered during the event**
  - ***Component*** **– specify associated part of device**
- **H6: Evaluation Codes**
  - **Methods, Results, Conclusions**

* 3500A Form http://www.fda.gov/medwatch/safety/FDA-3500A_fillable.pdf

Developed as Open Terminology

- **MOU between FDA and NCI for NCI to provide vocabulary development expertise**
- **Freely Available in hierarchical format in NCI Thesaurus, Metathesaurus and UMLS and on FDA Website**
- **Change Control Board**
- **Collaboration with ISO 19218; Future work with ISO 11073?**

CDRH Event Problem Codes

- **Questions about Using Codes**
  - **cdrh.eventcode@fda.hhs.gov**
- **Questions about Codes as Standard**
  - **Terrie Reed – terrie.reed@fda.hhs.gov**