

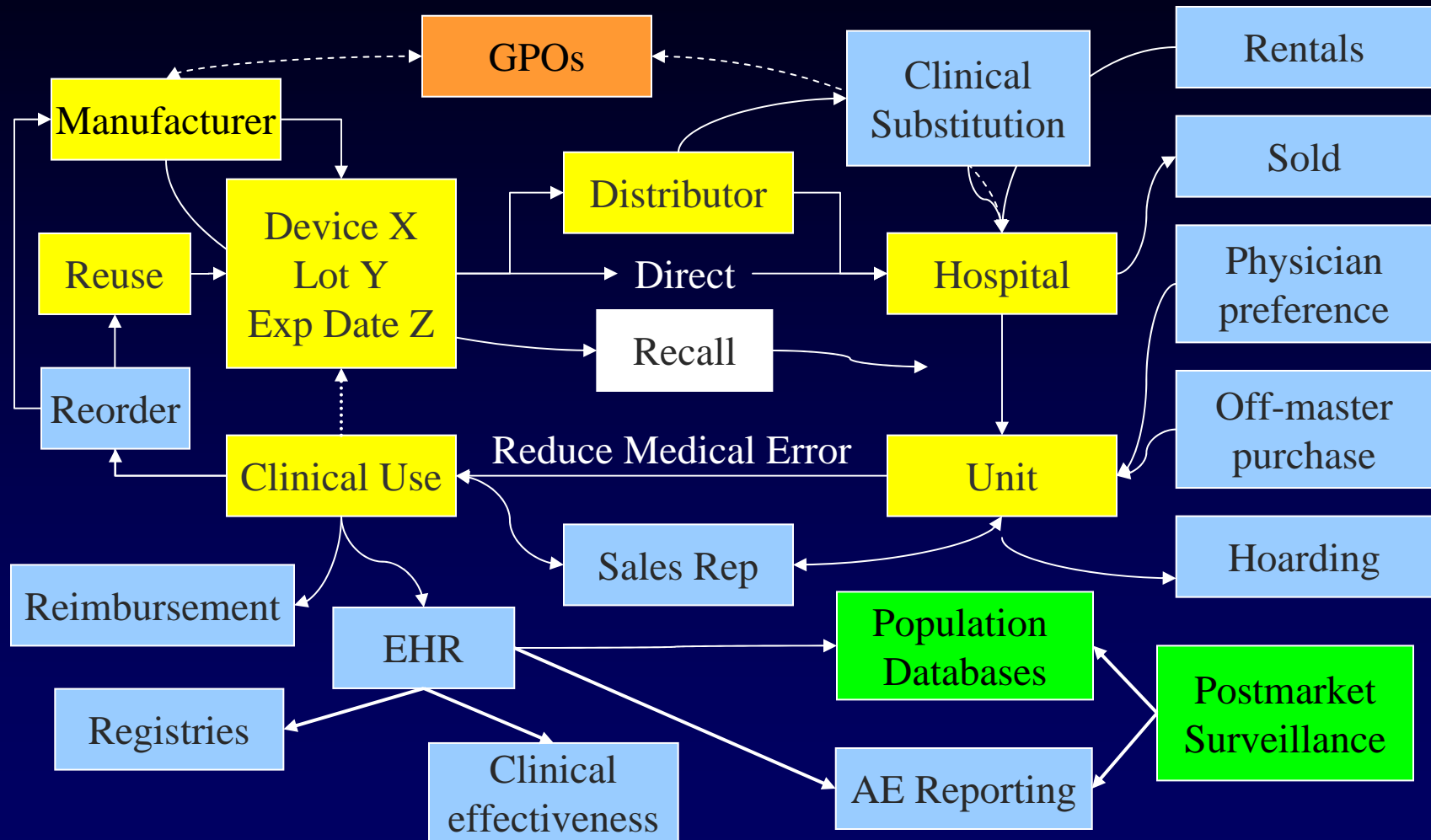
**Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.**

**Niccolo Machiavelli (1532)**

# The Integration of UDI – When the Real Benefits Start

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# Device Information Lifecycle



# 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

# Current Device Identification

Business Name	Item Number Type	Item Number
<b>BD</b>	<b>Mfg Catalog Number</b>	<b>329461</b>
<b>BD</b>	<b>GTIN</b>	<b>00382903294619</b>
<b>BD</b>	<b>GTIN</b>	<b>30382903294610</b>
<b>BD</b>	<b>GTIN</b>	<b>50382903294614</b>
<b>Cardinal Health</b>	<b>PV Order Number</b>	<b>BF329461</b>
<b>Owens &amp; Minor</b>	<b>PV Order Number</b>	<b>0722329461</b>
<b>Owens &amp; Minor</b>	<b>PV Order Number</b>	<b>0723329461</b>
<b>American Medical Depot</b>	<b>Vendor Catalog Number</b>	<b>777127217</b>
<b>American Medical Depot</b>	<b>Vendor Catalog Number</b>	<b>777127218</b>
<b>Government Sci Source</b>	<b>Vendor Catalog Number</b>	<b>FSC1482679CS</b>
<b>Government Sci Source</b>	<b>Vendor Catalog Number</b>	<b>FSC1482679PK</b>
<b>Alliance Joint Venture</b>	<b>Vendor Catalog Number</b>	<b>888021932</b>
<b>Thomas Scientific</b>	<b>Vendor Catalog Number</b>	<b>8938M25</b>
<b>Thomas Scientific</b>	<b>Vendor Catalog Number</b>	<b>8938M28</b>
<b>VWR International</b>	<b>Vendor Catalog Number</b>	<b>BD329461</b>

# 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

# UDI Can Improve... Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anti-counterfeiting/diversion
- Clinical/cost effectiveness (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

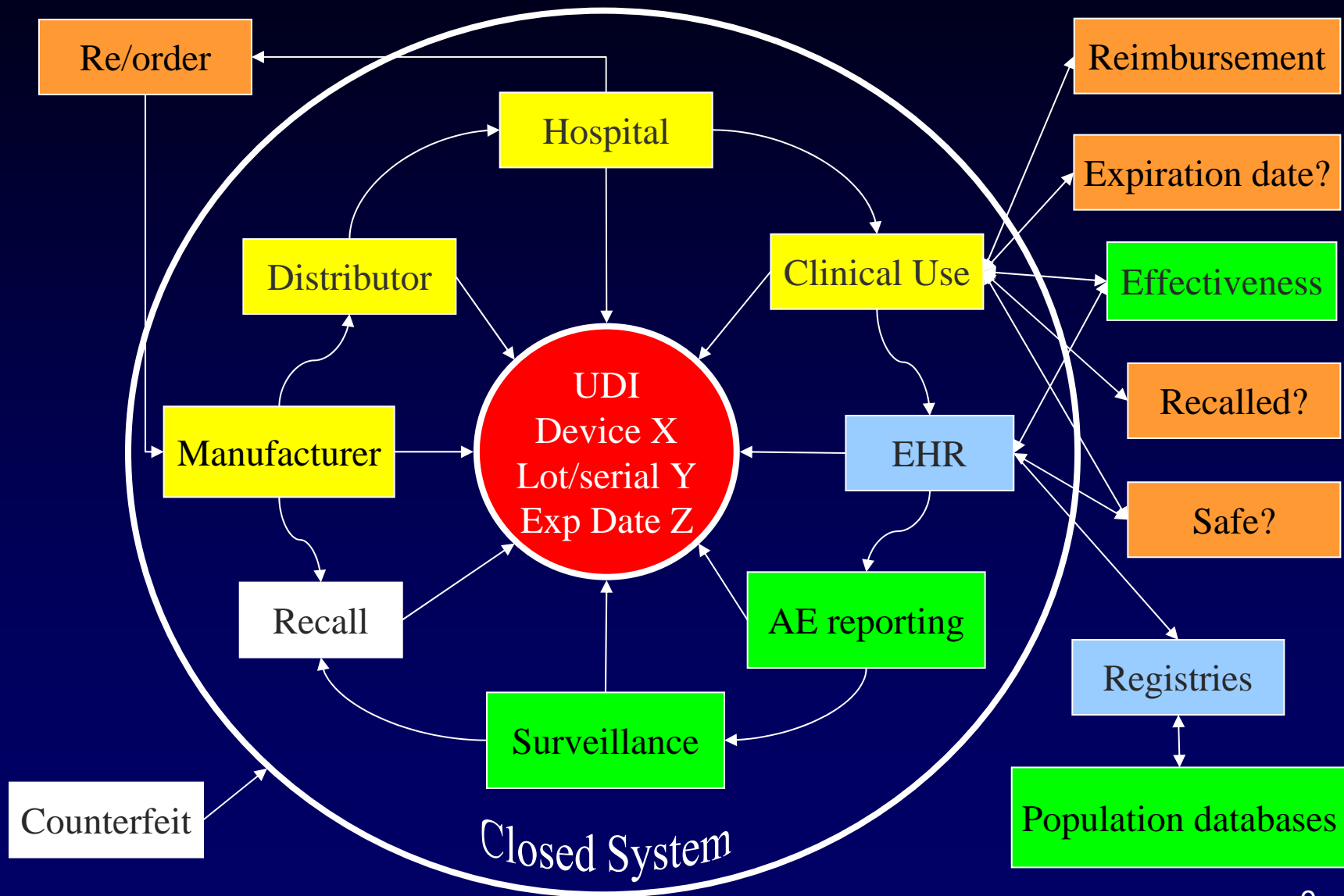
Develop a system to identify medical devices, which is:

- 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



# Medical Device Adverse Events

For 2007, we received ~ +100k reports

- ~ 15% lacked model or catalogue number
- ~ 50% lacked lot or other identifier
- ~ 10% lacked both

The face of things to come...

(01)00802526255410(17)080531(10)6062151

# Medical Device Recalls (2007)

- 41 Class I recalls
- 931 Class II recalls
- 78 Class III recalls
- Class I – 28M units (devices by lots, kits, etc)  
Range 4-27M (Moistureplus Solution)
- For March 2007 – 142 Class II recalls  
35M individual units (just one month)  
Range 1-33M (Lifescan one touch test strips)

# 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
- Last meeting Berlin 25-26 August 2009
- Final recommendations to SC at Nov 09 Meeting

# 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

# 1<sup>st</sup> – Developing the UDI

- Develop UDI code according to GS1, HIBCC, NDC
- 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)

# UDI Application - DPM

- Ceramics, titanium, plastics and stainless steels can all be direct part marked.
- Marks are durable enough to withstand harsh environments, including cleaning with disinfectants and steam sterilization.
- 2D datamatrix codes allow the marking of 20 or more characters onto spaces only a few millimetres across
- For very small marks - “local” vs global marking?

## 2<sup>nd</sup> – 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

**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

**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

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

**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 150PLB02 Rev.D


**ENDOPATH®**

# dextrus

## Finger-Mounted Locking Forceps

REF	FMF02	
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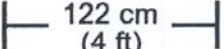


# UDI Application Example

 **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 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



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

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

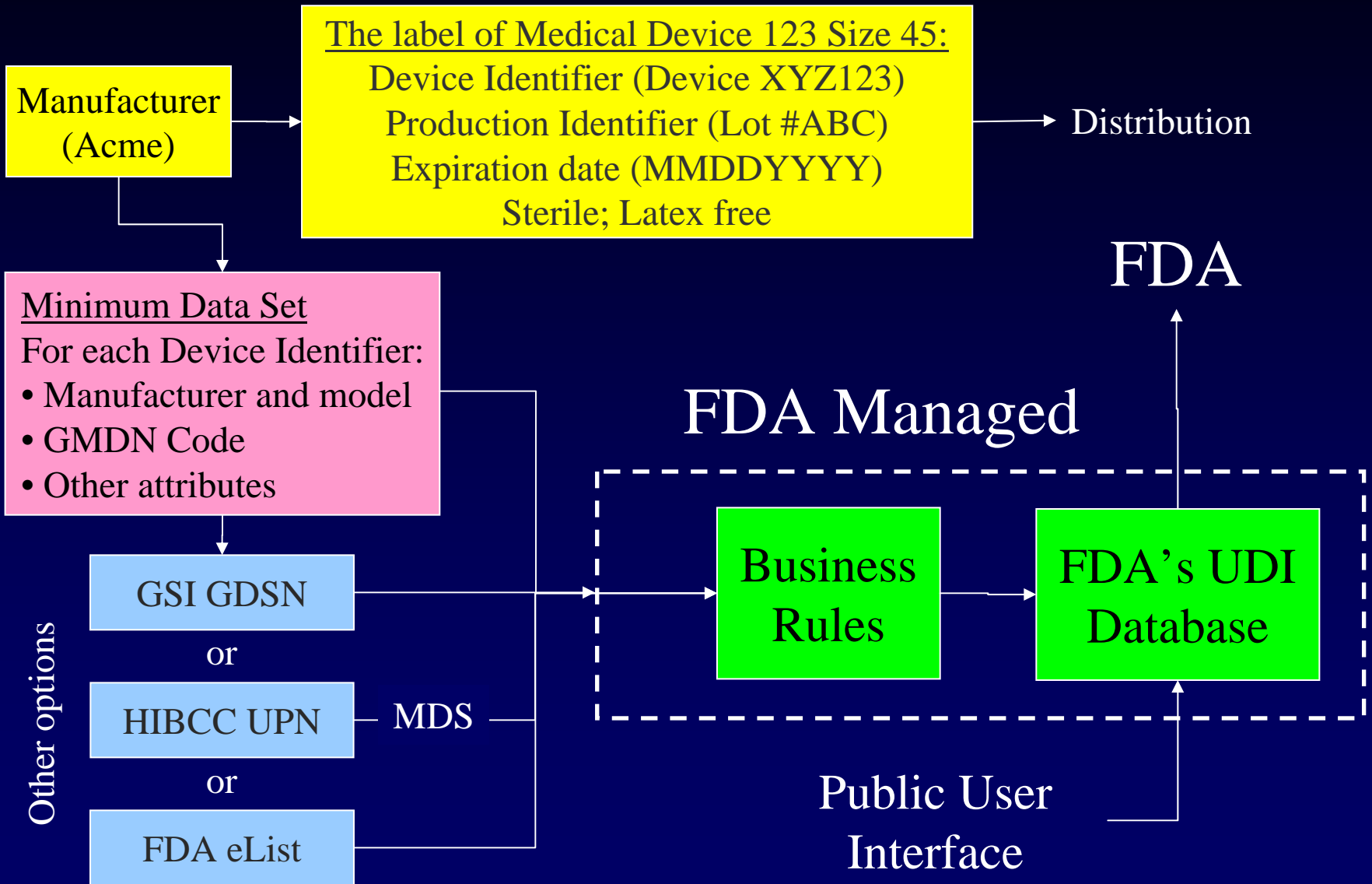
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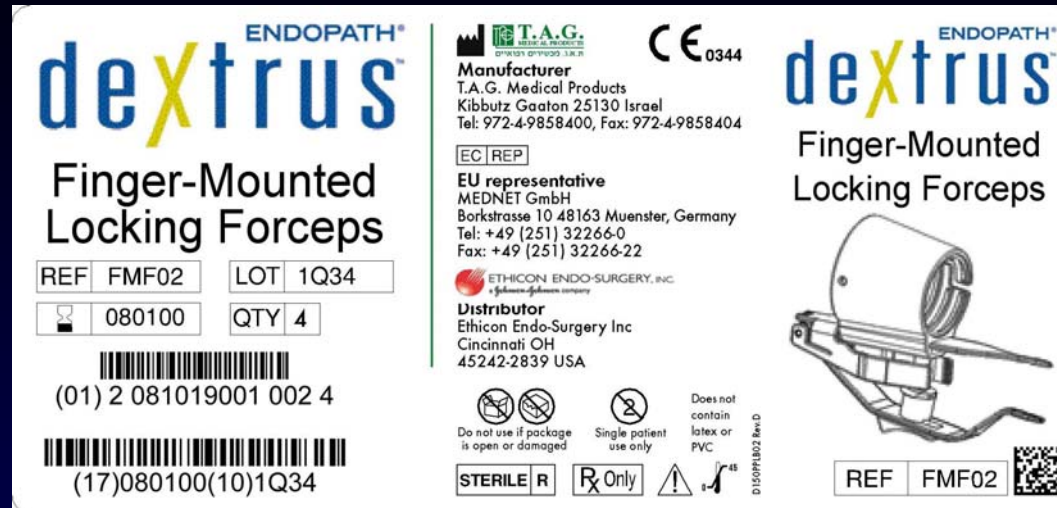
Manufactured for: Medtronic, Inc. Minneapolis, MN 55432 USA			
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## 3<sup>rd</sup> - UDI Database Development

- Device Identifier Type/Code [GTIN, HIBCC, NDC]
- Make/model; Brand Name; Long/Short Description
- Unit of Measure/Packaging level/quantity
- Control – Lot and/or Serial Number; Exp. Date
- Contact name, phone, email
- Device status (prescription or over-the-counter)
- GMDN Classification code/term
- Country of Origin Code/manufacture/Intended sale
- Storage conditions; Single Use/reusable; Sterility
- Contains known, labeled allergen (e.g., latex)

# FDA's UDI Database



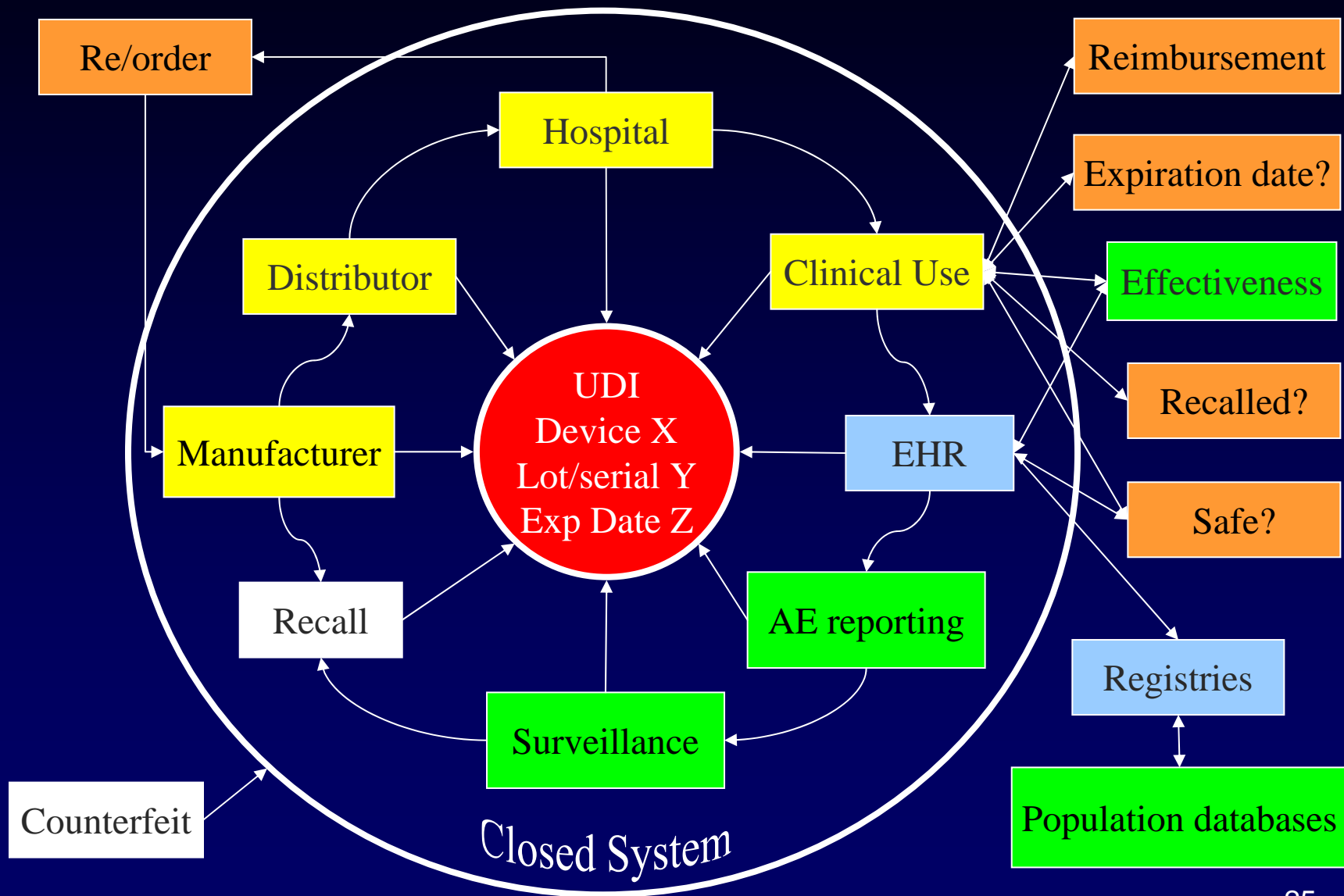


- Device Identifier: GS1 2081090010024
- Endopath Dextrus Finger Mounting Locking Forceps
- Ethicon Endo-Surgery Inc, Cincinnati, Ohio
- Jane Smith; 1-888-888-8888; JSmith@JNJ.com
- Controlled by Lot; Expiration Date
- Packaged sterile; Single Use; Prescription
- GMDN code: 12345; Manufactured in Israel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

# Adoption and Implementation

- Technology issues/role of technology – barcodes, RFID, DPM
- Distributor uptake and use
- Hospital uptake and use
- Use of UDID
- Medical error reduction (e.g., latex)
- Integration issues – MMIS-Clinical
- EMR
- Reimbursement
- Privacy

# Future Information Lifecycle



# 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.**

# Data Integration

- UDI will facilitate the integration of data across disparate systems – including supply chain, clinical, and reimbursement.
- With this integration comes insight and visibility to assess the cost and clinical effectiveness of:
  - devices in certain patient populations,
  - of similar technologies, and
  - of particular environments and users.

# Comparative Effectiveness

“What if it finds that some brand-new and incredibly expensive treatments are wildly effective... That could raise spending...” [TWP, 9/20/09]

- Will visibility will lead to the commoditization of all devices and less reimbursement...?
- Insight could lead to better (higher) utilization and reimbursement for those devices with a proven track record of better patient outcomes and lower overall healthcare costs.

# 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)