Unique Device Identification Update on FDA Activities

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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.

FDA Amendments Act of 2007

Establish a unique device identification system:

- Requires that the label of devices bear a unique identifier ["Label" is defined as "…a display of written, printed, or graphic matter upon the immediate container of any article."];
- Allows FDA to describe an alternative placement (e.g., on the device itself or its packaging) for a particular device or device type;

FDAAA of 2007 (continued)

Establish a unique device identification system:

- Allows FDA to exempt a particular device or type of device from the UDI requirements;
- The UDI must adequately identify the device through distribution and use; and
- The UDI includes information on the lot or serial number.

Establishing a UDI System

Combination of 3 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

1st – Developing the UDI

The UDI could be constructed by:

- Using ISO/IEC 15459-4:2006 "Information Technology – Unique Identifiers, Part 4: Unique identifiers for supply chain management"
- Concatenating Device and Production Identifier
- Device Identifier: Manufacturer, make, model and critical attributes
- Production Identifier: if currently serialized – serial number; if currently identified at the lot, the lot number, expiration date, or some combination.

2nd – UDI Application

The UDI could be:

- applied at the "patient use level" ("unit of use");
- created and maintained by the manufacturer; and
- be human readable and/or encoded in a form of automatic identification technology; however
- no specific technology would be identified (technology neutral).

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

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CE 0344

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Single patient use only

Does not contain latex or PVC

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Rx Only

0-45

D150PPLB02 Rev.D

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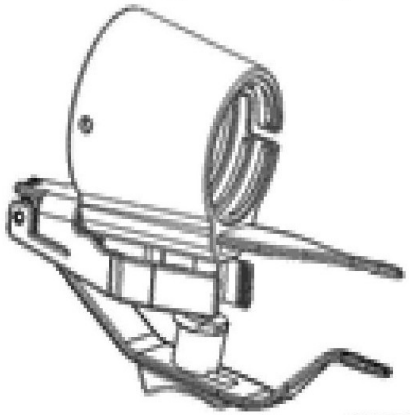
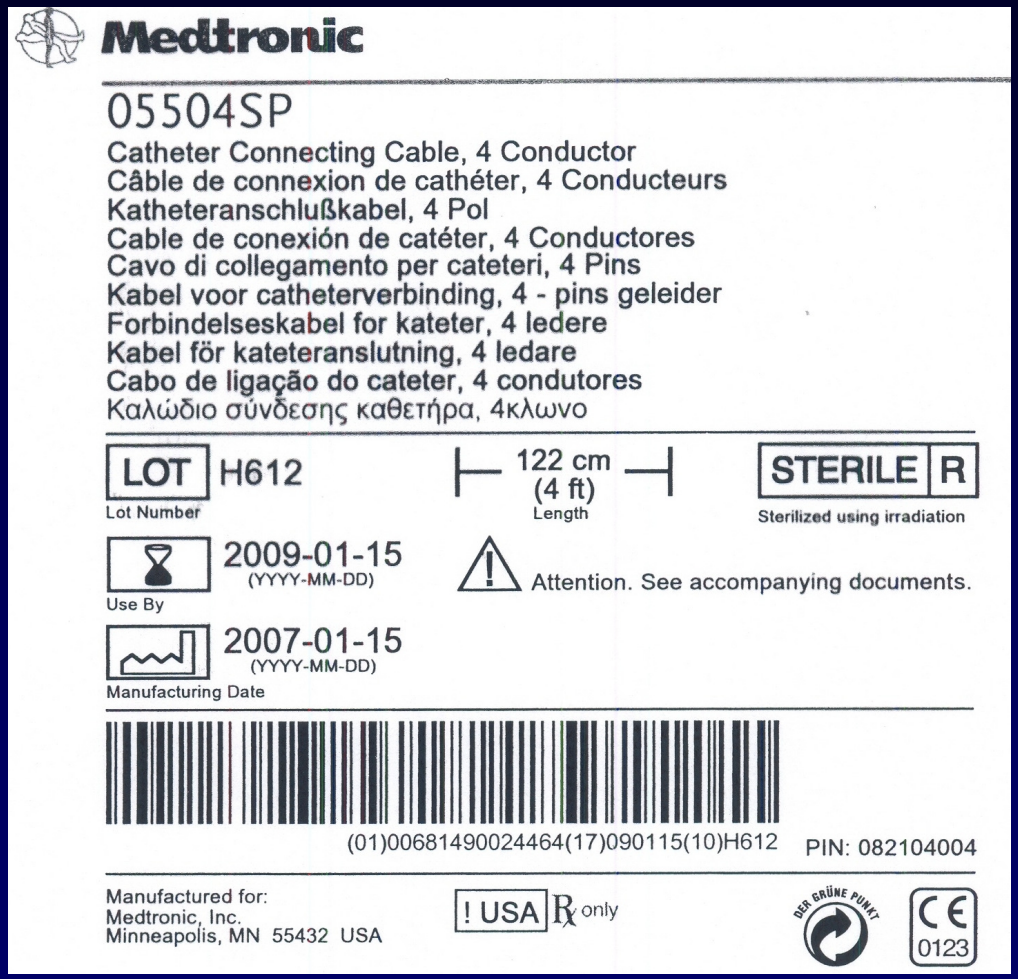


REF FMF02

UDI Application Example



3rd – UDI Database

Minimum Data Set for each **Device Identifier**:

- Device identifying information (e.g., manufacturer, make, model, size);
- Global Medical Device Nomenclature (GMDN);
- Other FDA identifying information (premarket authority, listing).
- Certain additional attributes – e.g., allergens (e.g., latex), compatibility issues single use/reusable; and… ???

Other UDI Issues

- AutoID technology issues
- Kits; combination products; legacy devices
- Re/marking (legally) reprocessed SUDs
- Maintaining dynamic information
- Hospital and other healthcare facility uptake
- Remanufactured and refurbished devices
- Triggers requiring a new UDI
- Maintaining “dynamic” device information
- Complex, multi-system (“capital”) devices
- Harmonized/international database

Unique Device Identification

www.fda.gov/cdrh/ocd/udi/

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