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.
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;
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:

- 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.
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

Finger-Mounted Locking Forceps

Manufacturer
T.A.G. Medical Products
Kibbutz Gaaton 25130 Israel
Tel: 972-4-9858400, Fax: 972-4-9858404

EU representative
MEDNET GmbH
Borkstrasse 10 48163 Muenster, Germany
Tel: +49 (251) 32266-0
Fax: +49 (251) 32266-22

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 RX Only

(01) 2 081019001 002 4
(17) 080100(10) 1Q34
UDI Application Example

![UDI Example Image]
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/
Email: cdrhudi@fda.hhs.gov