FDA believes that UDI can...

- Reduce device related medical errors - identify compatibility and interoperability issues, e.g.:
  - right device for right patient (latex allergy)
  - right accessory for right device
  - MRI compatibility
- Improve identification of specific device in adverse event reports
- Facilitate more effective device recalls – identify and locate recalled devices in a timely fashion
UDI can also…

- Facilitate the population of device use information in Electronic Medical Record Systems (HIT)
- Provide ancillary benefits:
  - Improve materials management and associated healthcare cost savings
  - Help track devices and identify counterfeit devices
  - Identify similar or substantially equivalent devices to avoid shortage
  - Emergency preparedness – national, military
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;
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.
Developing the UDI

The UDI would be constructed by:

• Concatenating the Device Identifier and the Production Identifier
  
UDI = Device Identifier + Production Identifier

• **Device Identifier:** Manufacturer, make, model and critical attributes [e.g., GS1 GTIN]

• **Production Identifier:** if currently serialized – serial number; if currently identified at the lot level, the lot number, expiration date – or some combination.
UDI Application

The UDI would be:

- applied at the “patient use level” (“unit of use”);
- created and maintained by the manufacturer;
- constructed following GS1 or HIBCC standard for device identification; and
- be human readable AND encoded in a form of automatic identification technology; however
- no specific technology would be identified (technology neutral).
UDI Database (1/2)

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

- Device identifying information (e.g., manufacturer, make, model, size);  
- Global Medical Device Nomenclature (GMDN);  
- Accessory Information (accessories needed to operate the device, or, the specific device it operates with); and  
- Other FDA identifying information (premarket authority, listing).
Certain additional attributes to facilitate safe use:

• Allergens (e.g., whether it contains latex);
• Compatibility issues (is it MRI compatible);
• Single use/reusable; and
• If reusable, how to reprocess.
• and … ???
Other UDI Issues

- NDC/NHRIC issues
- AutoID or human readable only?
- Combination products
- Reprocessed Single Use Devices (SUDs)
- Legacy devices
- Capital equipment; components; configurable devices
- Tracking/maintaining dynamic information (e.g., recalls, software version)
- Hospital and other healthcare facility uptake
Unique Device Identification
www.fda.gov/cdrh/ocd/udi/
Email: cdrhudi@fda.hhs.gov