Unique Device Identification (UDI) System Regulatory Overview

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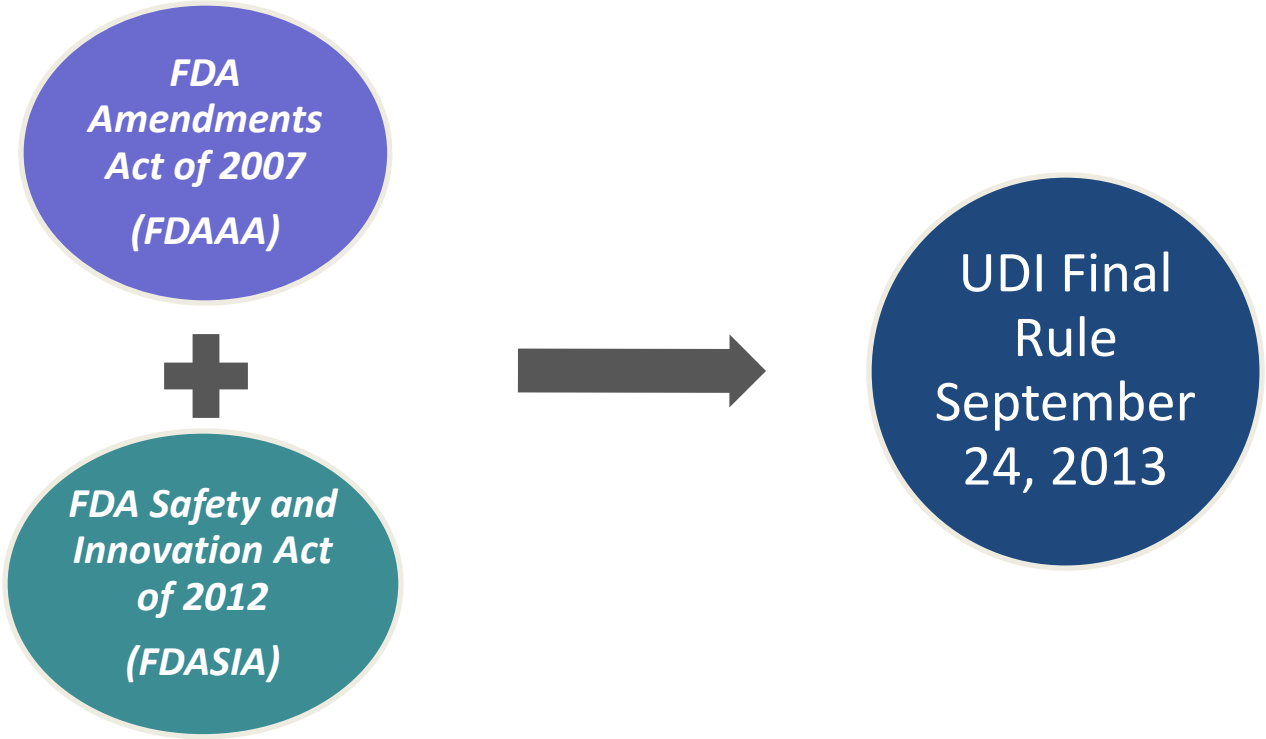
Learning Objectives

- Recognize the four steps of the UDI System
- Understand the labeler requirements
- Know the UDI compliance dates
- Identify UDI adoption benefits

Statutes and Regulation



Objective of the UDI Program

"Establish a system to adequately identify devices through distribution and use"

- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries

Four Steps to a Successful UDI Program

- Develop a standardized system to create the UDI
- Place UDI on label and (sometimes) the device
- Create and maintain the Global UDI Database
- Facilitate UDI Adoption and Implementation

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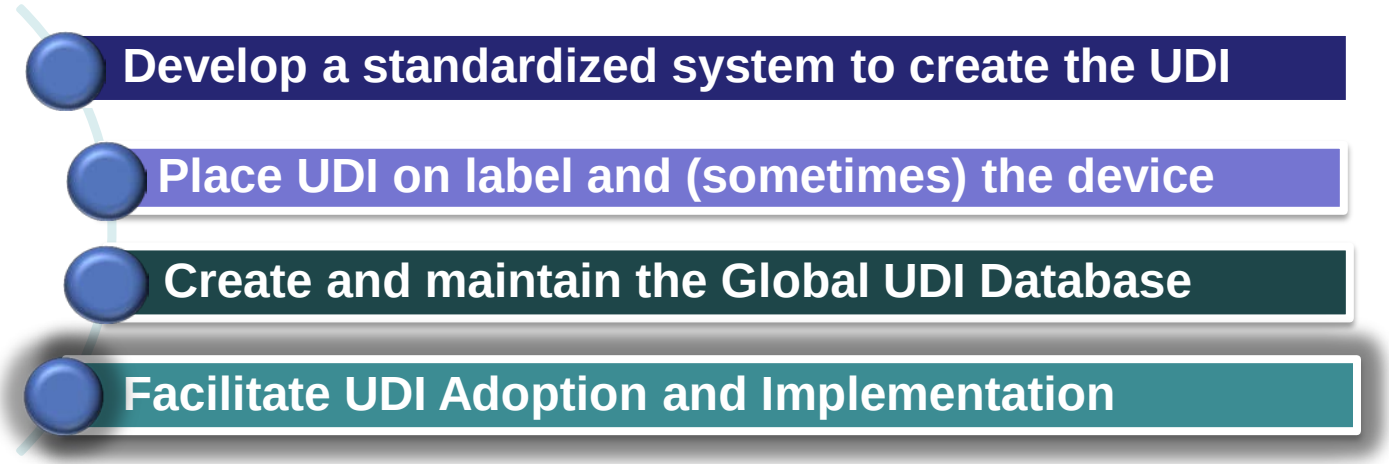


What is a Label?

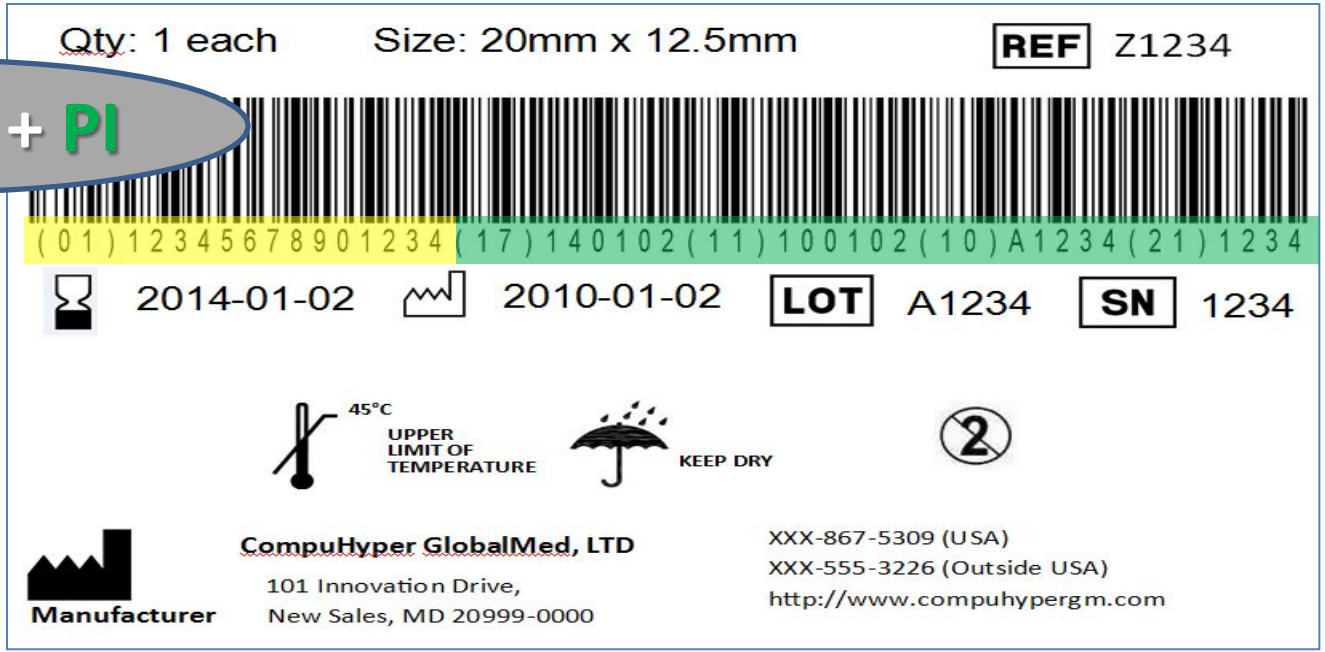
"Label" means a "display of written, printed, or graphic matter upon the immediate container of any article…"
21 USC 321(k)

What is a UDI?

Required on the device label, packages or, in some cases, on the device itself

Code in plain text and machine readable format (AIDC)

UDI = DI + PI



Device Identifier (DI)

Mandatory, fixed portion of UDI

- **Identifies:**
  - **Labeler of device**
  - **Specific version or model of device**
  - **Never changes once assigned**

Entered in Global UDI Database (GUDID)

- **GUDID serves as the repository of key device identification information**
- **DI is the unique key**

Production Identifier (PI)

Conditional, variable portion of UDI

- Not required for Class I devices

May include (when on the device label):

- Lot, batch, serial number
- Expiration date, date of manufacture
- HCT/P's regulated as devices: the required distinct identification code

Device Package

A device package contains a fixed quantity of a particular version or model of a device

Each level of the package requires a different UDI

Package Levels

Package Configuration of the Base Package

Base Package
Primary DI = 1001

Catheter, 12 Fr, 1 each
Device Count = 1

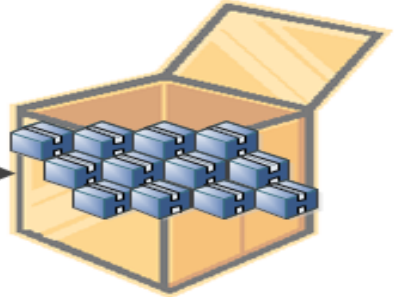
Package DI =2001

Catheter, 12 Fr, Box of 30
Contains 30 units of
Base Package DI 1001
Quantity per package = 30

Package DI =2002

Catheter, 12 Fr, Box of 50
Contains 50 units of
Base Package DI 1001
Quantity per package = 50

Package DI =3001



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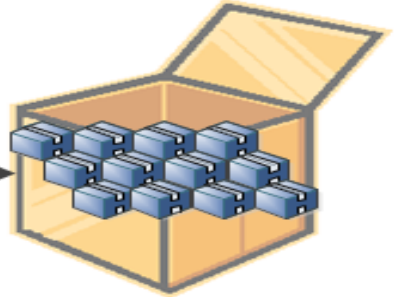

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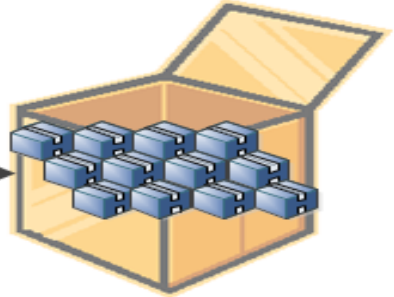

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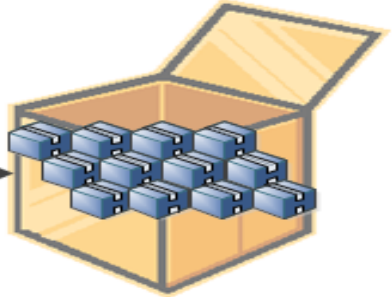

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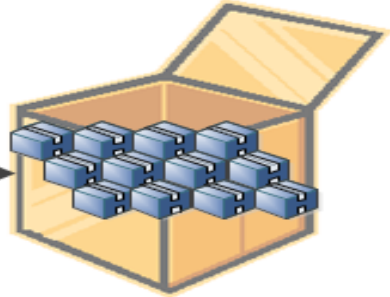

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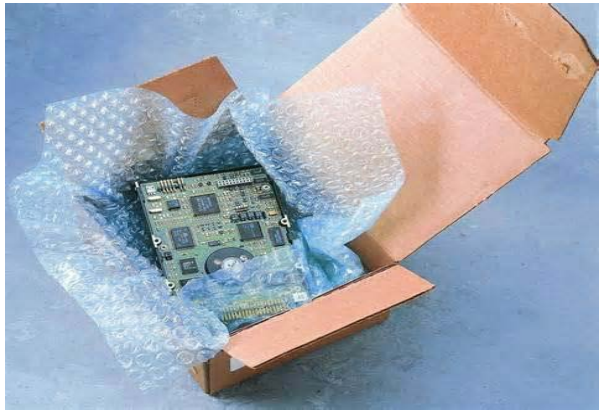
Shipping Containers are Not Device Packages and Do Not Require a UDI



Direct Marking

In addition to its label, the device itself must also bear a permanent mark UDI if the device is:	• Intended to be used more than once, and • Intended to be reprocessed before each use
UDI may be provided through either or both of the following:	• Easily readable plain text • Automatic Identification and Data Capture (AIDC) technology or any alternative technology that will provide UDI on demand
The direct mark UDI may be:	• Identical to UDI that appears on the label of the device, or • Different UDI used to distinguish the unpackaged device from any device package containing the device

What is a Labeler?

Labeler is responsible for UDI requirements

Defined under 21 CFR 801.3 as

any person who causes a label to be:

- Applied to a device with the intent that the device will be commercially distributed; or
- Replaced or modified with the intent that the device will be commercially distributed

Examples of Labelers

- Manufacturer (usually)
- Contract Manufacturer
- Private label distributor
- Convenience Kit Assembler

Quick Summary

Up Next ➡ **How UDIs are created**

Issuing Agencies

UDI regulations require:

- UDIs must be issued under a system operated by an FDA-accredited issuing agency
- Issuing Agency's system must conform to the ISO standards incorporated into the UDI Rule
- Accreditation is granted for an initial term of 3 years
  - May be renewed
  - May be revoked by the FDA

Issuing Agencies and Labelers

Labelers are required to:

- Work with at least one accredited Issuing Agency
- Use the Issuing Agency rules to build their UDI

Please see the FDA website for the list of currently accredited Issuing Agencies

Date Formats

Dates on the device label must be in specified format

2014-01-30

Summary of Basic UDI Requirements

Device label and device packages must bear a UDI

Key data for these devices must be submitted to GUDID

GUDID Global Unique Device Identification Database

- Repository of key device identification information
- Contains ONLY the DI; PIs are not submitted to nor stored in the GUDID
- Contains only PI flags to indicate which PIs are on the device UDI

GUDID Search and Retrieval

- **May 4, 2015: Launch of Beta AccessGUDID**
  accessgudid.nlm.nih.gov

- **Partnered with the National Library of Medicine (NLM) to provide:**
  - Public Search
  - Database Download
  - Web Services

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

- **Releasable attributes of Published DI records are available**

Compliance Dates for UDI Requirements

Device	Label/GUDID/Date Format Compliance Date
Class III (including Class III I/LS/LS[1]) Devices licensed under the PHS Act	September 24, 2014
Implantable, Life-Supporting and Life-Sustaining (Class II, Class I & Unclassified)	September 24, 2015
Class II (other than I/LS/LS[1])	September 24, 2016
Class I or Unclassified (other than I/LS/LS[1])	September 24, 2018

[1] Implantable/Life-Supporting/Life-Sustaining

Link: Details on Compliance Dates

Key General Exceptions

General exceptions from UDI requirements include*

- Class I cGMP exempted devices
- Individual single-use devices sold and stored in a single package until removed for use
- IDEs or devices used solely for nonclinical use
- Devices intended solely for export from the US
- Individual devices in convenience kits
- Three year “grandfather”

*See 21 CFR 801.30 for full list of exceptions

Exceptions and Alternatives

General exceptions under 21 CFR 801.30

FDA may grant an individual exception or alternative

Submit exception and alternative requests to the UDI Helpdesk

UDI Benefits

UDI assigned to devices	Clearly identify the device
Integrate UDI into electronic health information	Link data sources to improve data capture, device evaluation and decision-making
DI as key to unlock standard data	GUDID as authoritative source for key identification attributes

UDI Benefits

More rapid and accurate device data capture and retrieval for patient care

GUDID attributes as basis for clinical decision support – MRI, Latex, Sterile

More accurate reporting of adverse events, better recall management, better comparative data

Key Benefits of UDI

Patient Safe.

Improve Patient Safety

More Accurate Understanding of Device Benefit-Risk Profile

Facilitate Device Innovation and Patient Access

Strengthening our National Medical Device Evaluation System

Summary

- ✓ Remember the Four Steps of the UDI System
- ✓ Understand the UDI Labeler Requirements
  - ✓ Label and Date Format
  - ✓ GUDID Data Submission
- ✓ Know the UDI Compliance Dates
- ✓ Keep in mind the UDI Benefits

FDA UDI Website: www.fda.gov/udi

Providing Industry Education

1. **CDRH Learn – Multi-Media Industry Education**
   - over 80 modules - videos, audio recordings, power point presentations, software-based "how to" modules
   - accessible on your portable devices: http://www.fda.gov/Training/CDRHLearn
2. **Device Advice – Text-Based Education**
   - comprehensive regulatory information on premarket and postmarket topics: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance
3. **Division of Industry and Consumer Education (DICE)**
   - If you have a question - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Live Agents 9am – 12:30 pm; 1-4:30 pm EST)
   - **Web Homepage:** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm