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

- **FDA Amendments Act of 2007 (FDAAA)**
- **FDA Safety and Innovation Act of 2012 (FDASIA)**
- **UDI Final Rule**
  - **September 24, 2013**
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

1. Develop a standardized system to create the UDI
2. Place UDI on label and (sometimes) the device
3. Create and maintain the Global UDI Database
4. 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

Base Package
Primary DI = 1001

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

Package DI = 2001

Catheter, 12 Fr, Case of 360
Contains 12 units of
Package DI 2001
Quantity per package = 12

Catheter, 12 Fr, 1 each
Device Count = 1

Package DI = 2002

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

**Package Levels**

**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**
- Catheter, 12 Fr, Case of 360
- Contains 12 units of Package DI 2001
- Quantity per package = 12
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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

UDI = DI + PI

Labels → Packages → Labelers

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
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


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

- Releasable attributes of Published DI records are available
## Compliance Dates for UDI Requirements

<table>
<thead>
<tr>
<th>Device</th>
<th>Label/GUDID/Date Format</th>
<th>Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class III (including Class III I/LS/LS(^1))</td>
<td></td>
<td>September 24, 2014</td>
</tr>
<tr>
<td>Devices licensed under the PHS Act</td>
<td></td>
<td>September 24, 2015</td>
</tr>
<tr>
<td>Implantable, Life-Supporting and Life-Sustaining (Class II, Class I &amp; Unclassified)</td>
<td></td>
<td>September 24, 2016</td>
</tr>
<tr>
<td>Class II (other than I/LS/LS(^1))</td>
<td></td>
<td>September 24, 2018</td>
</tr>
<tr>
<td>Class I or Unclassified (other than I/LS/LS(^1))</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) 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

- 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