UDI Regulatory Basics
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Congress: Unique Device Identification Authority

- Label of devices to bear a unique identifier
- Unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number
Basic Requirements Under the UDI Rule

- Device label and device package must bear a UDI, 21 CFR 801.20

- Devices intended to be used more than once and intended to be reprocessed before each use must be directly marked with a UDI, 21 CFR 801.45

- Data for these devices must be submitted to Global Unique Device Identification Database (GUDID), 21 CFR 830.300

- Dates on the labels must be in correct format, 21 CFR 801.18
Devices Subject to UDI Requirements

- Apply to **devices** put in commercial distribution after the applicable compliance date

  ...instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, ... or accessory...

  ...distribution of a device intended for human use which is held or offered for sale...
Objectives of UDI

Establish a system to identify medical devices through distribution and use

- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Allow more accurate reporting, reviewing, and analyzing of adverse event reports
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries
- Enable more effectively managed medical device recalls
Four Steps to a Successful UDI Program

1. Develop a standardized system to create the UDI
2. Implement UDI labeling requirements
3. Create and maintain GUDID
4. Adoption and implementation by all stakeholders
# Compliance Dates for UDI Requirements

<table>
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<tr>
<th>Compliance Date</th>
<th>Must bear a UDI &amp; submit data to GUDID</th>
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| September 24, 2014    | • Class III devices, including class III stand-alone software  
                        • Devices licensed under the PHS Act |
| September 24, 2015    | • Implantable, life-supporting and life-sustaining (I/LS/LS) devices, including stand-alone software  
                        • Direct Marking of LS/LS devices, for certain intended uses |
| September 24, 2016    | • Class II devices  
                        • Direct Marking for class III devices and devices licensed under the PHS Act, for certain intended uses |
| September 24, 2018    | • Class I devices and devices not classified as class I, II or III  
                        • Direct Marking of class II devices for certain intended uses |
| September 24, 2020    | • Direct Marking of class I devices and devices not classified into class I, II or III, for certain intended uses |
Immediately In Effect (IIE) Guidance

- Enforcement discretion for UDI labeling and direct marking for class I and unclassified devices

- For devices manufactured and labeled after 9/24/2018:
  - Labeling Due 9/24/2020; Direct Mark 9/24/2022

- For devices manufactured and labeled prior to 9/24/2018:
  - Labeling Due: 9/24/2021; Direct Mark 9/24/2022.
Labeler

- Labeler responsible for UDI requirements
- Defined under 21 CFR 801.3
- Causes label to be applied, replaced, or modified
- 1 labeler per DI
- Should be indicated in the Device Master Record (DMR)
Form of a Unique Device Identifier (UDI)

UDI = DI + PI

• Placed on the device label and device packages
  – Easily readable plain-text and
  – Automatic identification and data capture (AIDC) technology
• Some devices must be directly marked with a UDI
Device Identifier (DI)

- Mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device
- Entered in GUDID
Production Identifier (PI)

Conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

- Lot or Batch
- Serial Number
- Expiration Date
- Manufacturing Date
- Distinct Identification Code

(21 CFR 1271.290(c))
Requirements for a UDI

UDI must:

• Be issued under a system operated by an FDA-accredited issuing agency

• Conform to each of the following international standards:
  – ISO/IEC 15459-2
  – ISO/IEC 15459-4
  – ISO/IEC 15459-6

• Use only characters and numbers from the invariant character set of ISO/IEC 646
Form & Content of a UDI Guidance

• Form of a UDI
  • Disclosure of Presence of AIDC
• Content of a UDI
  • Data Delimiters
  • Order of data in UDI carrier
FDA-Accredited Issuing Agencies

- GS1
- HIBCC
- ICCBBA

- Operates a system for the issuance of UDIs
- Systems conform to certain international consensus standards
Identifying a Device

• Only 1 DI from any particular FDA-accredited issuing agency may be used to identify a particular version or model of a device.
  – may be identified by UDIs from 2 or more different FDA-accredited issuing agencies.
Purpose of UDI

• A UDI on every device label and device package is required to ensure proper identification of the device at the:

  Point of Distribution  Point of Use
Basic Requirements Under the UDI Rule

1. Device label and device package must bear a UDI, 21 CFR 801.20

2. Devices intended to be used more than once and intended to be reprocessed before each use must be directly marked with a UDI, 21 CFR 801.45

3. Data for these devices must be submitted to Global Unique Device Identification Database (GUDID), 21 CFR 830.300

4. Dates on the labels must be in correct format, 21 CFR 801.18
Label to Bear a UDI

• The label of every medical device and every device package shall bear a UDI, unless excepted
  – Shipping container does not require a UDI
  – General exceptions under 21 CFR 801.30
  – Labelers may submit a request for an exception or alternative under 21 CFR 801.55
Device Label

- Under FD&C Act, Sec 201(k), the term "label" means a “display of written, printed, or graphic matter upon the immediate container of any article…”

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Device Package

• Under 21 CFR 801.3, Device Package means a package that contains a fixed quantity of a particular version or model of a device
Shipping Container

- Under 21 CFR 801.3, Shipping Container means a container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another.
Basic Requirements Under the UDI Rule

- Device label and device package must bear a UDI, 21 CFR 801.20
- Devices intended to be used more than once and intended to be reprocessed before each use must be directly marked with a UDI, 21 CFR 801.45
- Data for these devices must be submitted to Global Unique Device Identification Database (GUDID), 21 CFR 830.300
- Dates on the labels must be in correct format, 21 CFR 801.18
Direct Marking

- Device must also bear a permanent marking providing the UDI on the device itself 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;
  - AIDC technology, or any alternative technology, that will provide UDI on demand
Final Guidance: Direct Marking

• Affixing a UDI permanently on the device itself
  – Last throughout the expected use life of the device

• Definitions for:
  – “Intended to be used more than once”
  – “Reprocessing”
Intended to Be Used More than Once

- Intended for repeated uses on or by different patients
  - Ex: where a device is cleared or approved and labeled for repeated uses on or by different patients
Reprocessing

• Validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent use
  – Cleaned + high level sterilized/disinfected: a lethal process utilizing a sterilant under less than sterilizing conditions.
Direct Marking Compliance Dates

• Class I and unclassified devices: September 24, 2022
  – Applies to devices manufactured before or after September 24, 2018 compliance date specified in the UDI Rule.
Exceptions from Direct Marking

Direct marking requirements shall not apply to any device that meets any of the following criteria:

- Would interfere with the safety or effectiveness
- Not technologically feasible
- Device is a single-use device and is subjected to additional processing and manufacturing for the purpose of an additional single use
- Device has been previously marked under 21 CFR 801.45(a)

*Exception to be noted in design history file
### Basic Requirements Under the UDI Rule

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Global Unique Device Identification Database (GUDID)

- The labeler shall submit data to GUDID no later than the date the label of the device must bear a UDI
  - 15 calendar days from the date a new version or model enters commercial distribution

- GUDID Data Elements Table

- Submit to FDA an update to the information required by 21 CFR 830.310
Basic Requirements Under the UDI Rule

1. Device label and device package must bear a UDI, 21 CFR 801.20
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Date Format

• Printed dates on medical device labels must be in format: YYYY-MM-DD (digits only)
  Ex: 2018-04-24

• Applies to all medical devices, even those not required to bear a UDI unless excepted.

• Exceptions: Combination products that properly bear NDC & certain electronic products
  – see 21 CFR 801.18(b)
Requesting an Exception or Alternative

Exception

UDI requirement *not technologically feasible*

Alternative

Alternative provides for a *more accurate, precise, or rapid device identification*

Alternative would *better ensure safety or effectiveness* of device
Help Desk Exceptions/Alternatives Inquiry Form

All fields are required.

Type: Exception Request
First Name: First Name
Last Name: Last Name
Organization: Organization
Email: Email
Phone: Phone
Subject: New Exception or Alternative Inquiry

Submit
Rescinding NHRICs & NDCs for Medical Devices

• Use of National Health Related Items Code (NHRIC) and National Drug Code (NDC) numbers for devices is being phased out over a time period that corresponds with the UDI compliance
• Applies to all medical devices
• Enforcement policy has changed
Enforcement Policy on NHRIC and NDC Numbers Assigned to Devices

- Agency’s intent not to enforce before September 24, 2021, the prohibition against providing NHRIC or NDC numbers on device labels and device packages.
- Agency’s intent to continue considering requests for continued use of FDA labeler codes under a system for the issuance of UDIs until September 24, 2021
Specific Types of Devices
Stand-Alone Software

• Medical software that is itself a medical device and is not a component, part, or accessory of a medical device

All stand-alone software must provide UDI though easily readable plain-text statement displayed when software is started or through a menu command

If distributed in packaged form
• Must bear UDI on device label and device packages
• Must convey version number in its PI if version number on label

If not distributed in packaged form
• Must convey version number in its PI
Version Number for Stand-Alone Software

- Falls within the meaning of lot or batch for **stand-alone software**
- **Lot or batch** means one finished device or more that consist of a single type, model, class, size, composition, or **software version** that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.
HCT/Ps

• Human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device must comply with UDI requirements

• Same UDI requirements as other medical devices, with the addition of PI:
  – Distinct Identification Code
    • Donation Identification Number, Lot Number, Serial Number
Class I Devices

Subject to UDI requirements, with certain exceptions:

• Class I devices are not required to include a PI
• Class I device may bear a UPC on their labels and device packages
  – Must submit data to GUDID
• Class I GMP exempt devices are excepted entirely from UDI requirements

Note: Class I 510(k) exempt devices are not generally excepted
Humanitarian Use Devices

- Not generally excepted
- Same UDI requirements as class III medical devices
General Exceptions
21 CFR 801.30
Existing Inventory Exception

• A finished device manufactured and labeled prior to the UDI compliance date
  – Exception for class I / unclassified devices expires:
    – September 24, 2021 for labeling and
    – September 24, 2022 for Direct Marking.
Single-Use Devices

- Individual single-use devices, all of a single version or model, that are distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution are not required to bear a UDI on the label of the device.
  - Device package containing these individual devices must bear a UDI.
  - Exception not available for any implantable device.
Custom Device

A custom device within the meaning of 21 CFR 812.3(b) is not required to bear a UDI:

1. Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;

2. Is not generally available to, or generally used by, other physicians or dentists;

3. Is not generally available in finished form for purchase or for dispensing upon prescription;

4. Is not offered for commercial distribution through labeling or advertising; and

5. Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.
Exported Devices

• A device intended for export from the U.S. is not required to comply with the UDI requirement
Combination Products

If a combination product properly bears a **NDC** number on its label:

- Combination product does not require a UDI
- Device constituents must bear a UDI, unless combination product is a single entity [21 CFR 3.2(e)(1)]

If a combination product properly bears a **UDI** on its label:

- Devices packaged within immediate container of combination product does not require a UDI
Convenience Kits

• Device packaged within the immediate container of a convenience kit is not required to bear a UDI if the label of the convenience kit itself bears a UDI

• Comprehensive session on Kits and FDA Guidance related to them on Day 2 at 10:30am.
Other General UDI Exceptions

• Device used solely for research, teaching, or chemical analysis, and not intended for any clinical use
• Investigational device within the meaning 21 CFR part 812
• Veterinary medical device
• Device held by the Strategic National Stockpile and granted an exception or alternative under 21 CFR 801.128(f)(2)
• Device for which FDA has established a performance standard under section 514(b) of the FD&C Act and has provided an exception
Voluntary Compliance with UDI Requirements

UDI labeling
- 21 CFR 801.20

GUDID data submission
- 21 CFR 830 Subpart E
A New DI is Required if:

- Change to a device that results in a new version or model
  - Version or model means all devices that have specifications, performance, size, and composition, within limits set by the labeler
- Create a new device package
  - New device count
- Relabel device
  - Device labeled by a new labeler
Vision for UDI Adoption

UDI Labeled Device to Care Provider

Company submits data to GUDID

Device used on patient

GUDID as source of standard device information

Document Device Use
UDI Resources

www.fda.gov/udi

• Final Rule
• GUDID Data Elements Reference Table- March 30, 2018
• GUDID User Manual
• UDI Formats by FDA-Accredited Issuing Agency- January 27, 2017
• Webinars and Trainings
UDI Guidance Documents

- GUDID Guidance- June 27, 2014
- UDI Small Entity Compliance Guide- August 13, 2014
- Unique Device Identification: Direct Marking of Devices – November 17, 2017
FDA UDI Help Desk

- Please complete all fields on the web form: [www.fda.gov/udi](http://www.fda.gov/udi)
Questions?

FDA UDI Help Desk: www.fda.gov/udi