FDA’s Unique Device Identification (UDI) System – The Final Regulation

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FDA’s UDI Final Regulation

- 2007 FDA Amendments Act of 2007
- 2012 July 10th – UDI *Proposed* Regulation Publishes
- 2012 July – FDASIA provisions added
- 2012 November 7th – original comment period closes
- 2012 November 19th – FDASIA amendment publishes
- 2012 December 19th – FDA ISA comment period closes
- 2013 UDI Final Rule and *draft* GUDID Guidance
Legislation (FDAAA 07; FDASIA 12)

Not later than December 31, 2012, the Secretary shall issue proposed 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. The Secretary shall finalize the proposed regulations not later than 6 months after the close of the comment period and shall implement the final regulations with respect to devices that are implantable, life-saving, and life sustaining not later than 2 years after the regulations are finalized, taking into account patient access to medical devices and therapies.
Overview

1. Standardized Date Format
2. Establishing a UDI System
3. Major changes from proposed to final rule
4. Draft Global UDI Database (GUDID) Guidance
Standardized Date Format

**Proposed rule** – required US format (Jun 19, 2013) and implementation in 1 year.

**Final rule** – if label includes a date (e.g., expiration):

- All numeric: YYYY-MM-DD (2013-06-19)
- Day must always be included
- **Same Compliance Date as other UDI requirements**
- If a device is not subject to UDI – date formatting requirements will apply at year 5
- A combination product with NDC number is exempt.
Establishing a UDI System

Combination of 4 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
4. Adoption and Implementation
What is a UDI?

- Code on the device label, packaging or product, in both plain text and machine readable format
- Two parts: UDI = DI+PI
  - **Device Identifier (DI) (static)** – specific to a device version or model
  - **Production Identifier(s) (PI) (dynamic)** – one or more currently used control/production information, such as lot/batch, serial number, manufacturing date, expiration date
1st – Developing the UDI

• FDA will accredit issuing agencies (ISO 15459) – e.g., GS1, HIBCC, ICCBBA
• Develop UDI code according to one of the standards
• Created and maintained by the manufacturer
• Concatenating Device and Production Identifier
2nd – UDI Application

- Unique UDI applied to “base package” AND higher levels of packaging
- Default location is the label
- Human readable and encoded in a form of automatic identification technology
- No specific technology (technology neutral)
- ALSO Direct Marking (DM) for device intended to be used more than once and reprocessed before each use
- Stand-alone software - means of displaying its UDI
General Exemptions

• Class I Devices do not need to include Production Identifiers in UDI.
• GMP-exempt Class I devices
• Individual single-use devices, 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 or sale.
UDI Application Example

MOSAIC® 305 CINCH® II

REF: 305C221
Size: 21 MM
Use By: 2016-07-12
Serial Number: 21A11F4855

MOSAIC® 305 CINCH® II
Porcine Bioprosthesis Aortic Valve

Aortic

STERILE LC
Device has been sterilized using Liquid Chemical Sterilants according to EN/ISO 14160.

P Y R O G E N
Nonpyrogenic

Do Not Reuse

USA Rx only
For US Audiences Only

Check temperature indicator prior to use

Temperature Limitation:
• 41 °F (5 °C)

Manufacturer:
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Manufactured at:
Santa Ana, CA, USA
© 2011 Medtronic
12115330C2 Rev. 1B

www.medtronic.com/manuals
Consult instructions for use
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

EC REP
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
# UDI Application Example

![Image of UDI label example](image)

## REF: 242406

<table>
<thead>
<tr>
<th>Electrode Width</th>
<th>Electrode Spacing</th>
<th>110 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 mm</td>
<td>2 mm</td>
<td></td>
</tr>
<tr>
<td>2 mm</td>
<td>9 mm</td>
<td></td>
</tr>
<tr>
<td>2 mm</td>
<td>2 mm</td>
<td></td>
</tr>
</tbody>
</table>

## No. of Electrodes: 24

## Contents:

- **Sterile**, non-pyrogenic unless package opened or damaged.

## Use by:

- **LOT**: XXXXXXXX
- **Year**: 2016
- **Month**: 01

## Manufacturer:

- **Bard Electrophysiology Division**
- **C.R. Bard Inc.**
- **96 Technology Drive**, **Lowell, MA 01851**
- **+1 978 441 6302** (All others)
- **www.crbard.com**
UDI Application Example

Donated Human Tissue
Human Allograft Tissue: Passes USP <71> Sterility Tests. Rx Only

DESCR: Demineralized Bone Strip

DIMEN: 5 cm x 5 cm
EXP: JAN 27, 2013
Store at ambient temperature. Do not freeze.

Treated with gamma radiation. Tissue is recovered under aseptic conditions. Tissue is aseptically processed and passes USP <71> Sterility Tests. Trace amounts of processing agents may remain. See package insert for these as well as for contraindications, warnings and preparation for use.

FOR SINGLE PATIENT USE ONLY

Generis Tissue Bank
Global Street
Any Town
Worldwide
Telephone: xxxxxxxx
Fax: xxxxxxxx
www.xxxxxx.org

ISBT 128
A999912123456 S X
Processor: A9997
Product: T6017
Product Supplementary: Z012
Division: 102

ISBT 128 Area of Label
ISBT128

Device Identifier (Static): A9997T9017Z012
- A9997 is the processor identifier assigned by ICCBBA ≡ manufacturer identifier
- T9017Z012 is the product identifier ≡ catalogue number

Production Identifier: A999912123456102
- A999912123456 is the donation identification number ≡ Lot no.
- 102 is the division number ≡ serial number
FDA’s Global UDI Database

Manufacturer (Acme) → The label of Medical Device 123 Size 45:
Device Identifier (Device XYZ123)
Production Identifier (Lot #ABC)
Expiration date (MMDDYYYY)

Commercial Distribution

Minimum Data Set
For each Device Identifier

Web based tool
or
HL7 SPL
3rd Parties

FDA Managed

Business Rules

FDA’s GUDID

Public User Interface
For each Device Identifier (DI) (*no PIs*):
• The proprietary/trade/brand name of the device,
• Previous DI if a new version or model
• The version or model number
• If direct marked, DI if different than label
• The size of the version or model
• The type of production identifiers on the label
• FDA premarket submission and listing number(s)
• Global Medical Device Nomenclature (GMDN) term
• FDA product code (procode)
• The number of individual devices in each package.
3rd – Global UDI Database (2/2)

- Commercial distribution status
- Higher levels of packaging
- Whether it is a kit; combination product; HCT/P

Whether the device is labeled:
- As sterile or sterilize before use (and how)
- As containing natural rubber latex,
- With MRI compatibility (safe, conditional, unsafe)
- As Rx and/or OTC
4th - Compliance Dates

• Explains when a labeler is required to comply with a regulatory requirement – proposed rule incorrectly used the term effective dates.

Implementation (compliance) timeframes are the same:
• Year 1: class III and devices licensed under PHS Act
• Year 2: class II implants and life-supporting/sustaining
• Year 3: rest of class II
• Year 5: class I
4th - Compliance Dates

The final rule has only two effective dates:
- 30 Days for exception requests and issuing agencies
- 90 days for all the rest

For Direct Marking:
- Compliance dates are extended by 2 years
- except for FDASIA (year 2) devices – still at year 2.
Exception to Compliance Dates

• FDA may grant a 1-year extension of the compliance date for class III devices or a device licensed under the PHS Act – when it is in the best interest of the public health.

• Provides an exception for a finished device that is manufactured and labeled prior to the compliance date – exception expires 3 years after the compliance date [existing inventory].
Conforming Amendments

• Part 803 – Medical Device Reporting
• Part 806 – Reports of Corrections And Removals
• Part 810 – Medical Device Recall Authority
• Part 814 – Premarket Approvals
• Part 820 – Quality System Regulation
• Part 821 – Medical Device Tracking Requirements
• Part 822 – Postmarket Surveillance
Changes from Proposed Rule

- Definitions
- UPC Exception
- Combination Products and Kits
- Packaged Single Use Devices (SUDs)
- Direct Marking
- Stand-alone Software
- Exceptions
- New Version or Model
- NDC/NHRIC Numbers
- Generic Symbol
- GMDN
- GUDID
Changes from Proposed Rule

Drivers for changes from Proposed rule:
• Simplification
• Reduce cost and burden
• Consistency
Labeler Definition

Any person who causes a label to be:

• applied to a device with the intent that the device will be **commercially distributed** (was in interstate commerce); or

• **replaced or** modified with the intent that the device will be commercially distributed.

Except – that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label.
Changed or Added Definitions

• **Shipping container** means a [package... or pallet] container used during the shipment or transportation of devices [from one point to another], and whose contents may vary from one shipment to another.

• **Version or model** means [a device package containing one or more] *all* devices that have specifications, performance, size, and composition, within [specified] limits *set by the labeler*. 
Changed or Added Definitions

- **Human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device** means an HCT/P as defined in § 1271.3(d) of this chapter that does not meet the criteria in § 1271.10(a) and that is also regulated as a device.

- **Also added production identifiers** - the distinct code that relates the HCT/P to the donor.

- **Universal product code (UPC)** means the product identifier used to identify [a company and product name of] an item sold at retail in the United States.
OTC-UPC Exemption

Proposed rule – would have provided an exception for all OTC devices, regardless of where distributed.

Final rule states:
- A class I device labeled with a UPC can use it as its UDI (UPC is the UDI, no additional PIs)
- Must meet all other UDI requirements – including GUDID submissions.
Combination Products

Proposed rule – would have required a UDI on:
• Combination products whose PMOA is a device, and
• Device constituent parts (except for those they were physically, chemically, or otherwise combined such that it is not possible for it to be used).

Final rule – a combination product must have a UDI:
• If it does, the device constituent parts are exempt.
• A combination product that has a NDC is exempt,
  • However, device constituents must have UDI (unless CP is a single entity).
Kits

Proposed rule – required a UDI on:
• the label and package of each device packaged in a convenience kit (except single use devices).

Final rule:
• Requires the label and each device package of every convenience kit to bear a UDI
• As long as label of kit has UDI, devices contained within a convenience kit are exempt from UDI.
Packaged SUDs

**Proposed rule** – allowed for:
- **class I** single-use devices (SUDs) – distributed together in a single device package – to have the UDI on the package and not individual device.

**Final rule** – extends this SUD exception to all classes.
- Modified exception only for devices that are “…intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution or sale.”
- Except implants.
Direct Marking

Proposed rule – required Direct Marking for:
• implantable devices,
• devices intended to be sterilized between patient use,
• stand-alone software.

Final rule – only requires Direct Marking for:
• Expanded sterilized devices to all devices that are intended to be used more than once and “reprocessed” (clean, disinfect or sterilize) before each use.
• Moves application to stand-alone software.
Direct Marking Exceptions

1. Direct marking would interfere with the safety or effectiveness of the device;
2. Direct marking is not technologically feasible;
3. The device is a single-use device
4. The device has been previously marked

Exception to be noted in design history file.
Stand-alone Software

- New section – explains how stand alone software can meet UDI labeling requirements when it is not distributed in package form:
- All stand-alone software to include means of displaying its UDI; and
- Stand-alone software that is distributed in both packaged form and in a form that is not packaged may be use same UDI.
- Compliance dates are the same as class compliance dates.
Exceptions

Clarified aspects of the exception/alternative processes:
• FDA may initiate and grant an exception or alternative – on our own or in response to a request.
• FDA may rescind an exception or alternative.
• FDA will make all decisions available on our website.
• Any labeler may use a granted exception or alternative.
Exception Process

1. Identify the device(s) subject to exception/alternative
2. Identify the provisions subject to the request
3. If exception – explain why the requirements are not technologically feasible.
4. If an alternative, describe the alternative and
   a. why it would provide for more accurate, precise, or rapid device identification – or
   b. how it would better ensure the safety or effectiveness of the device
5. Estimate the number of affected labelers and devices
New Version or Model

Proposed rule – required a new DI when a change to:
• Specifications, performance, size, or composition greater than the specified limits;
• Quantity in a package or a new package;
• Significantly affect the safety or effectiveness;
• Nonsterile to a sterile package, or vice-versa

Final rule – states that a new DI is required whenever:
• A change to a device results in a new version or model
• Create a new device package
• No relationship to premarket requirements.
NDC/NHRIC Numbers

Proposed rule was unclear about implementation.

Final rules states:
• Every NHRIC/NDC number assigned to any device (even a device that is not required to bear a UDI) will be rescinded no later than year 5.
• However, you may continue to use an FDA-issued (NHRIC) labeler code provided that the labeler submits a request for continued use within year 1.
Proposed rule:
• required use of a symbol to indicate the presence of AIDC technology, and
• provided a generic symbol.

Final rule:
• does not require use of a symbol to indicate the presence of AIDC technology,
• no longer provides for use of a generic symbol, and
• requires only that a label "disclose" the presence of AIDC technology.
MRI Compatibility

• **Proposed rule** – did not require information concerning magnetic resonance imaging (MRI) compatibility.

• **Final rule** – requires the submission to GUDID of MRI compatibility (Safe, Conditional, Unsafe) – if the device has been labeled.
GMDN

• Proposed rule stated that FDA would not use Global Medical Device Nomenclature (GMDN) unless freely available.

• GUDID will provide free access to GMDN Preferred Terms within the GUDID data submission process.
Draft GUDID Guidance

• Draft guidance – 60 day comment period
• Explain how interaction with the database will work:
  • GUDID Accounts Management module (DUNS structure, DUNS – match label, various user roles)
  • Device Identifier module/life-cycle, published records, grace period
  • Web interface and HL7 SPL
  • Search
• Comments welcome and future training
Initial GUDID Implementation

- Database access initially limited to Class III and PHS Act Device Labelers
- Encourage Class III to submit as early as possible
- Online Helpdesk and Data Stewards available to receive feedback
- Input by initial submitters will be invaluable for future enhancements

- www.fda.gov/udi will serve as the main portal for all GUDID information. Visit the website for GUDID information, checklists, and other helpful resources.
Submitting to the GUDID

Recommended preparatory steps to submit to GUDID
• Read the Final Rule and GUDID Draft Guidance
• Determine your primary submission option – GUDID Web Interface or HL7 SPL
• Read the HL7 SPL Implementation Guide, if applicable
  • Obtain an FDA ESG account and complete testing
• Identify/obtain DUNS numbers for your company
  • Verify information in the D&B database
• Obtain active GMDN preferred terms for your devices
• Identify/obtain correct Listing Number for your devices
• Request a GUDID Account
GUDID Web Interface

Secure online interface enables:
• Creation of GUDID Accounts for Labelers by FDA via the Account Management Module
• Labelers must request a GUDID Account
• Submission of device information one record at a time via the Device Identifier Module
• Search and Retrieval of published device information via the Search Module
GUDID HL7 SPL Submissions

- Enables submission of device identification information as xml files
- Utilizes Health Level 7 (HL7) Structured Product Labeling (SPL) standard
- Technical specifications are available via the GUDID HL7 SPL Implementation Package (www.fda.gov/udi)
- Must use the FDA Electronic Submissions Gateway (ESG) to transmit the file (See www.fda.gov/esg)
- **Must first establish a GUDID Account**
- Complete required testing prior to submitting to production system
Search and Retrieval

Two Search and Retrieval Options are available:

Web Interface Search and Retrieval
• Quick Search – enables search on device identifier, company name, brand name, version/model
• Advanced Search – additional attributes are available

System to System Search and Retrieval
• Web Services – accepts a Device Identifier Number and returns all relevant attributes.
• Database Download capability – planned for the future.
GUDID Search and Retrieval is temporarily disabled and will be enabled at a future date when the database is populated.
How to Contact Us

- Check UDI website - www.fda.gov/udi
- Regulatory questions – udi@fda.hhs.gov
- GUDID Technical Questions – visit www.fda.gov/udi, and click on the GUDID Help-Desk link.
- FDA ESG questions (HL7 SPL submission)
  - Policy questions – esgprep@fda.hhs.gov
  - Technical questions – esgreg@gnsi.com
- System Downtime Notification – visit UDI website for information about scheduled & unscheduled downtimes
- Sign up for GovDelivery for both program/regulatory information and GUDID system notifications