"…it can seldom be right… to sacrifice a present benefit for a doubtful advantage in the future… It is not wise to look too far ahead; our powers of prediction are slight, our command over results infinitesimal… We can never know enough to make the chance worth taking… There is this further consideration that is often in need of emphasis: it is not sufficient that the state of affairs which we seek to promote should be better than the state of affairs which preceded it; **it must be sufficiently better to make up for the evils of the transition**."

John Maynard Keynes
Burke's Timidity on Embarking on War (1904)

Not IF – but HOW…
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 (legislation)
- 2012 July 10th – UDI *Proposed* Regulation Publishes
- 2012 July – FDASIA provisions added (legislation)
- 2012 Nov 7th – original comment period closes
- 2012 Nov 19th – FDASIA amendment publishes (reg)
- 2012 Dec 19th – FDAISA comment period closes
- **2013 September 24th – UDI Final Rule/Regulation and *draft* GUDID Guidance**

Rule: https://federalregister.gov/a/2013-23059
Guidance NoA: https://federalregister.gov/a/2013-23058
Guidance: www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf

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

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**
- Applies to all labels (even if exempt from UDI)
- If not subject to UDI – applies at year 5
- A combination product with NDC number is exempt.

Establishing a UDI System

Combination of 4 distinct steps:

1. Develop standardized unique device identifiers (UDIs)
2. Put the UDI in human readable and AIDC on the label
3. Submit data to the Global UDI Database (GUDID)
4. Implementation timelines

What is a UDI?

Identifier/code on device label and packaging (and, in some cases, on the device itself)

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 identifiers that is lot/batch number, serial number, manufacturing date, expiration date
  - If on the label – then needs to be part of the PIs
  - Not requiring any changes to currently used PIs

UDI General Rule

- The label* of EVERY medical device (including all IVDs) must have a UDI.
- EVERY device package (contains a fixed quantity of a version or model) must have a UDI.

Any other approach is an exception to or alternative from these requirements.

* Section 201(k) defines 'label' as a display of written, printed, or graphic matter upon the immediate container of any article...

1st – Develop the UDI

- FDA will accredit issuing agencies (ISO 15459) – e.g., GS1, HIBCC, ICCBBA
- Created and maintained by the manufacturer
- Develop UDI code according to one (or more) of these global device identification standards (1/time)
- A DI can only identify a single model or version
- Only one DI from an issuing agency can be used to identify a particular version or model.
- UDIs from multiple IAs can be used on a device
- A DI can never be reused
- If relabeled, needs a new DI and record of previous

2nd – UDI Application

- Unique UDI applied to the label of the "base package*" AND (higher levels of) device packages
  * Base package is the lowest level of packaging required to have a (full, required) UDI
- Default location is the label
- Human readable and encoded in AIDC technology
- No specific technology (technology neutral)
- ALSO Direct Marking (DM) for device intended to be used more than once and ***reprocessed*** before use
- Stand-alone software - means of displaying its UDI

General Exemptions

- Class I Devices do NOT need to include PIs
- GMP-exempt Class I devices
- Existing inventory (finished device packaged and labeled prior to compliance date – 3 years)
- Shipping containers
- If UDI on kit/CP, components or CP constituent parts
- Individual single-use devices (SUDs):
  - distributed together in a single device package,
  - intended to be stored in that package until removed for use, and
  - which are not intended for individual distribution.
- and others…

UDI Application Example

MOSAIC® 305 CINCH® II

A

21 MM

REF → 305C221
Reorder Number

Size → 21 MM

Use By → 2016 – 07 – 12

SN → 21A11F4855
Serial Number

(01)00643169001763(17)160712(21)21A11F4855

MOSAIC® 305 CINCH® II
Porcine Bioprosthesis Aortic Valve

AOA®

Aortic

(01)00643169001763(17)160712(21)21A11F4855

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

PYROGEN
Nonpyrogenic

Do Not Resterilize

Do Not Reuse

: 1
Quantity

+5 °C +41 °F
+25 °C +77 °F
Temperature Limitation

! USA Rx only
For US Audiences Only

www.medtronic.com/manuals
Consult Instructions for Use

Check temperature indicator prior to use

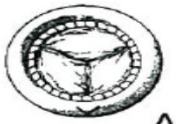
Manufacturer:
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Manufactured at:
Santa Ana, CA USA

1211533002 Rev. 1B

MOSAIC® 305 CINCH® II
Porcine Bioprosthesis Aortic Valve

AOA®



Aortic

UDI Application Example

ENDOPATH®

dextrus™

Finger-Mounted
Locking Forceps

REF	FMF02	LOT	1Q34
	080100	QTY	4

(01) 2 081019001 002 4

(17)080100(10)1Q34

T.A.G. MEDICAL PRODUCTS
ת.א.ג. מכשירים רפואיים

CE 0344

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

ETHICON ENDO-SURGERY, INC.
a Johnson & Johnson company

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 R

Rx Only

0-45

D150PPLB02 Rev.D

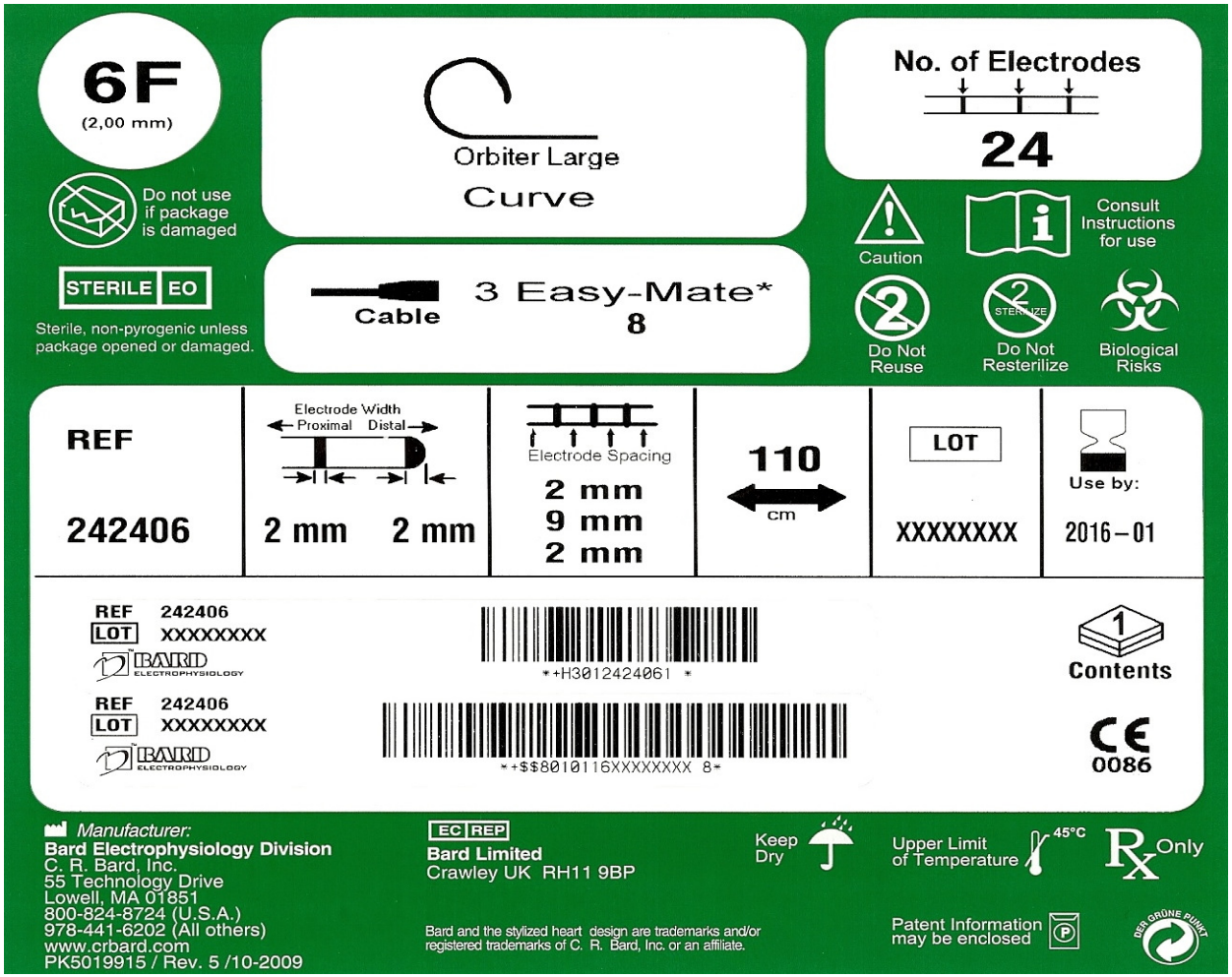
ENDOPATH®

dextrus™

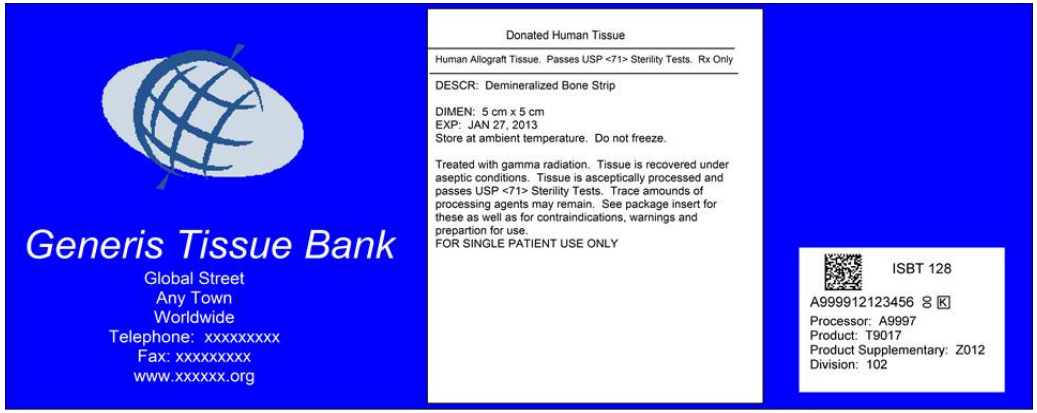
Finger-Mounted
Locking Forceps

REF FMF02

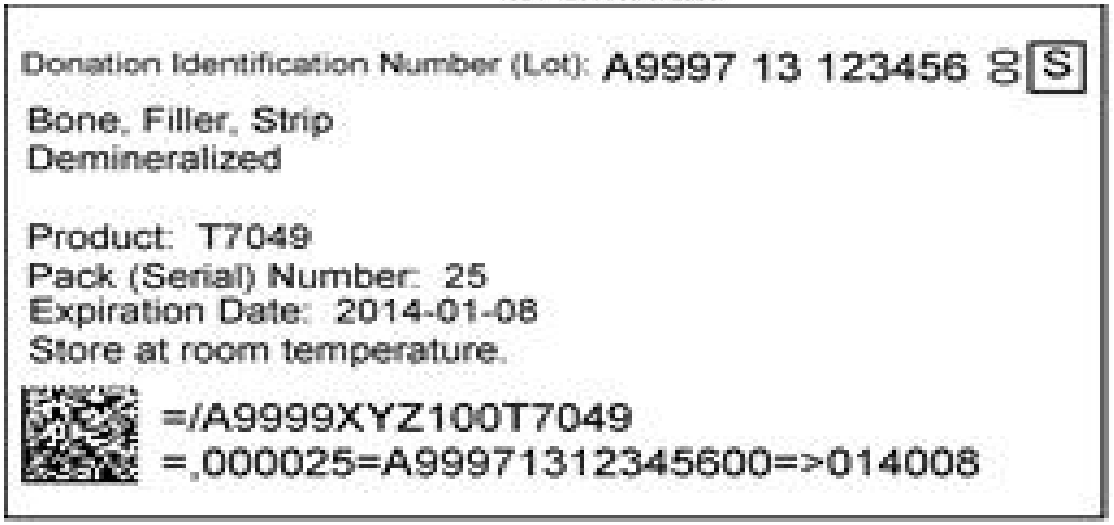
UDI Application Example



UDI Application Example



ISBT 128 Area of Label



ISBT128

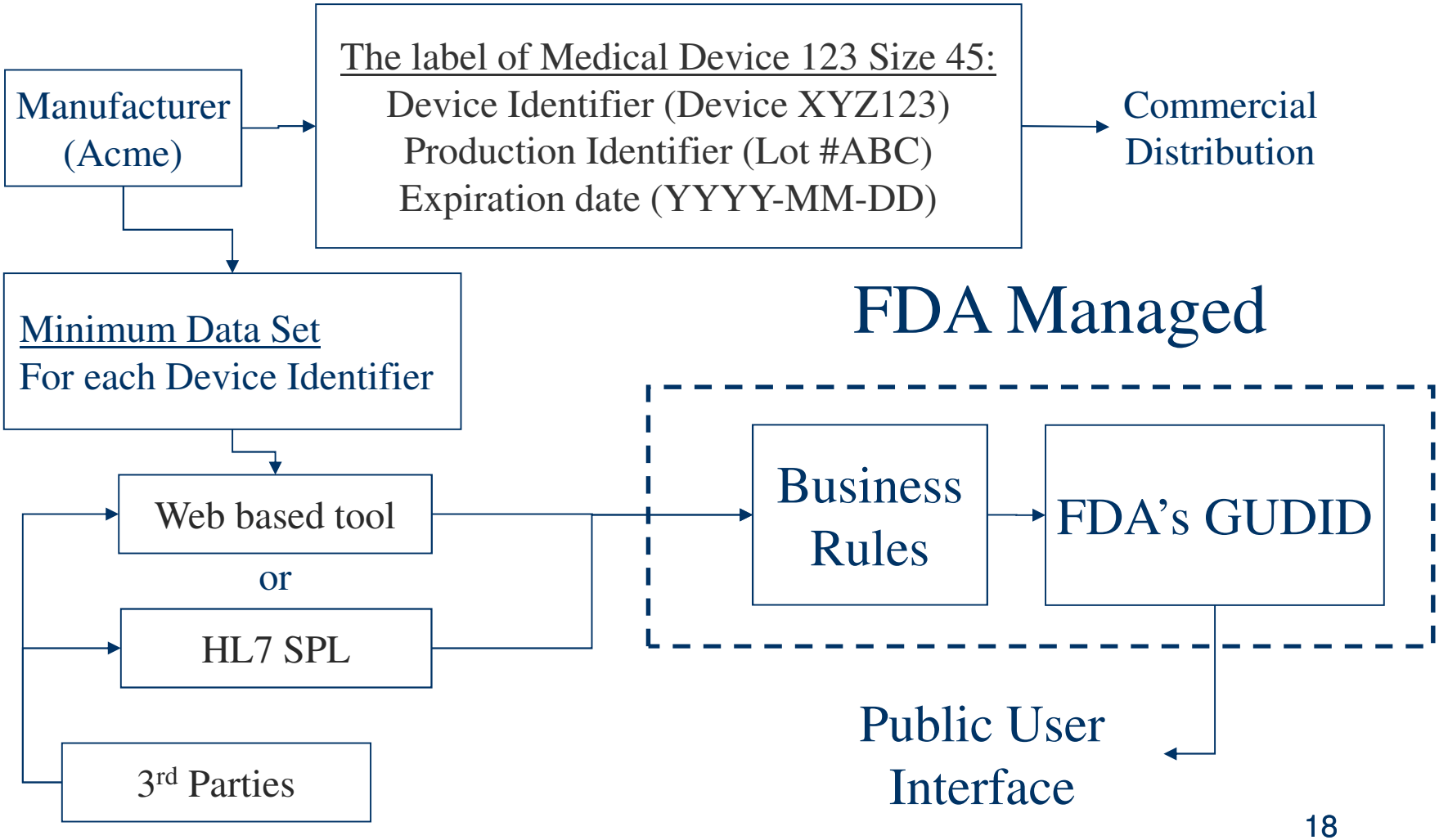
Device Identifier (Product Processor Identifier Code):
A9997T9017Z012

- 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



3rd – Global UDI Database (1/2)

For each and every Device Identifier (DI) (*no PIs*):

- The labeled proprietary/trade/brand name
- The labeled version or model number
- Previous DI if a new version or model
- 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

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.

Search and Retrieval

GUDID Search and Retrieval is temporarily disabled and will be enabled at a future date when the database is populated.

4th - *Effective* Dates

Effective vs. Compliance dates

The final rule has only two effective dates:

- 30 Days for exception requests and issuing agencies
- 90 days for all the rest

Compliance dates:

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

4th - *Compliance* Dates

Implementation (compliance) timeframes are the same:

- Year 1: class III and devices licensed under PHS Act
- Year 2: class II/I implants and life-supporting/sustaining
- Year 3: rest of class II
- Year 5: class I

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

Adds to each the requirement to use UDI:

- 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
- Issuing Agencies

Changes from Proposed Rule

Drivers for changes from Proposed rule:

- Simplification
- Reduce cost and burden
- Consistency
- Global Harmonization

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.

807.3 (b) Commercial Distribution

…means **any distribution** of a device… which is held or offered for sale but does not include the following:

1. Internal or interplant transfer between establishments within the same parent, subsidiary, and/or affiliate;
2. Any distribution which has an approved exemption for investigational use;
3. For foreign establishments, the distribution of any device that is neither imported nor offered for import into the United States.

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 UDI or PIs)
- Must meet all other UDI requirements – including GUDID submissions.
- Label/package can include both.

Combination Products

Proposed rule – would have required a UDI on:

- Combination products whose PMOA is a device, and
- **Device constituent parts** (except [single entity] 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 CP that properly bears a NDC is exempt,
  - But – then device constituents must have UDI
  - If CP is a single entity, then parts are exempt.

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."
- Not applicable to 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:

- Implantable device requirements removed.
- All devices that are intended to be used more than once and "reprocessed" (clean, disinfect or sterilize) before each use [expanded sterilized to reprocessed].
- Moves application to stand-alone software.

Directly Marked UDI

- May be identical or different from label UDI
- Either or both plain text and/AIDC

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 reprocessed single-use device
4. The device has been previously marked

Exception to be noted in design history file – do not need to submit exception request.

Stand-alone Software

New section – explains how stand alone software can meet UDI labeling requirements:

- Regardless of how distributed, all stand-alone software to include means of displaying its UDI As plain text UDI when started or menu command
- If distributed in packaged form, may use same UDI for both package and display.
- Compliance dates are the same as class compliance dates.

Exceptions

FR clarified aspects of the exception/alternative process:

- 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/Alternative 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:
A NHRIC/NDC number may no longer be used:

- When your device is subject to UDI, or
- If exempt, at year 5.

- However, labeler may continue to use an FDA-issued (NHRIC) labeler code (in another standard system) **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 that is not evident,
- 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.

Final Rule:

- Labelers should obtain appropriate GMDN PT codes from GMDN Agency.
- *Future* GUDID tool will enable users to select a GMDN preferred term, at no cost, to be used in their GUDID submission – until a GMDN PT code can be obtained from the GMDN Agency.

Issuing Agency Accreditation

- Proposed rule – a private *nonprofit* organization or *State agency* may apply for accreditation…

Final rule:

- A [any] private organization may apply for accreditation as an issuing agency.

and

- Will protect against conflicts of interest between the issuing agency and labelers… that may impede the applicant's ability to independently operate a fair and neutral identifier system.

How to Contact Us

- UDI Website is key resource – www.fda.gov/UDI
- Contact us: click on UDI Help Desk link for Regulatory and GUDID Questions
- Receive Notifications from us: click on Unique Device Identification: Get e-mail updates 
- Look for Schedule of planned and Notification of unplanned downtimes
- FDA ESG questions (HL7 SPL submission)
  - Policy questions – esgprep@fda.hhs.gov
  - Technical questions – esgreg@gnsi.com