The Global Language of Business

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UDI regulation & implementation in U.S.

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Nothing is more difficult to undertake, more perilous to conduct or more uncertain in its outcome, than to take the lead in introducing a new order of things. For the innovator has for enemies all those who have done well under the old and lukewarm defenders amongst those who may do well under the new.

Niccolo Machiavelli

(1523)

US FDA's UDI Regulation
Implementation, Progress and Issues to Date

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US FDA's UDI Implementation

- Overview of US FDA UDI
- Overview of labels and packaging
- UDI responsibility and assignment
- Barcode verification
- GUDID data
- Conforming amendments
- Summary
- Q & A

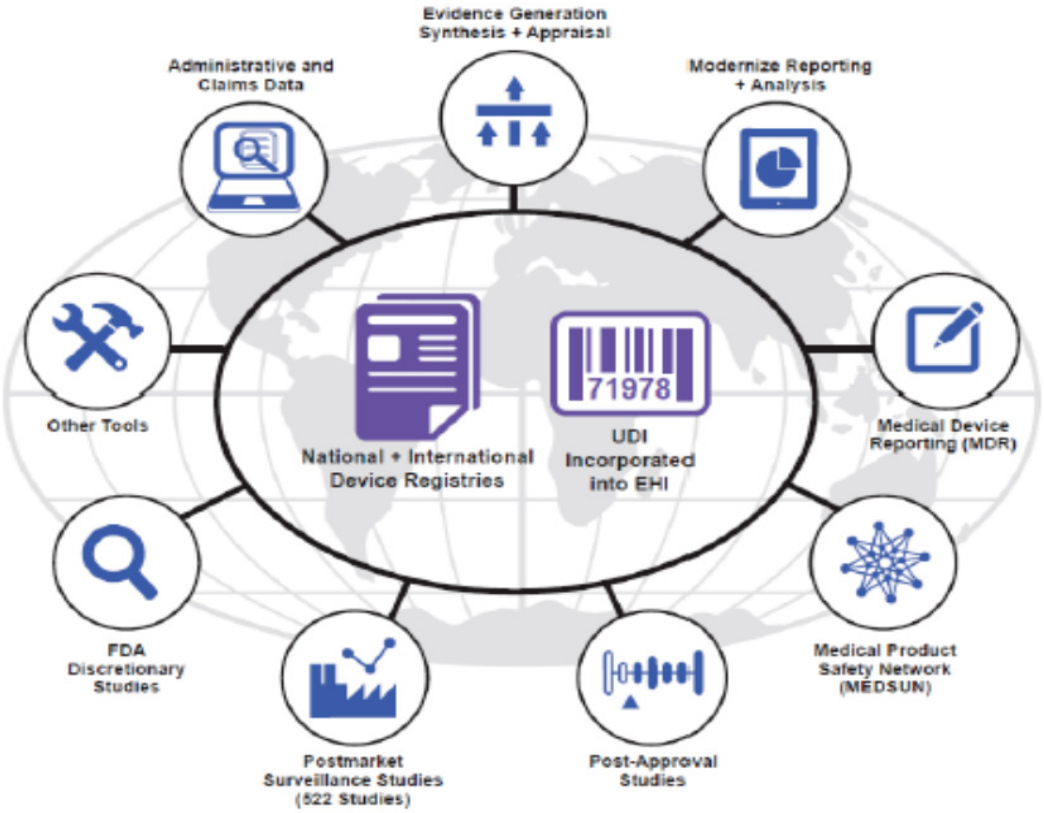
US Legislation (FDAAA 07; FDASIA 12)

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.*

US FDA UDI Rule Intent/Objective

- Provide standardized granular identification of medical devices and associated meta-data to support various public-health initiatives
- Most notably FDA's postmarket surveillance activities – including:
  - Adverse event reporting/aggregation
  - Device and disease specific registries
  - Large population-based data sets, e.g., claims data
  - Device identification in registries
  - Comparative effectiveness
  - Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
  - Sentinel Initiative, CDRH National Medical Device Postmarket Surveillance Plan and other postmarket surveillance activities

National Medical Device Postmarket Surveillance Plan



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.
- “Shipping containers” (a container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another) are exempt.
- 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...

What is a medical device?

A device is … "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, **including a component part, or accessory** which is… intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals….

Also see many conversations about

- (Configurable) Systems
- Combination products

Accessories <….> of Parent Devices

- ***support*** the performance of a parent device by enabling or facilitating that device to perform according to its intended use.
- ***supplement*** the performance of a parent device if it adds a new function or a new way of using the parent device, without changing the intended use of the parent device.
- ***augment*** the performance of a parent device by enabling the device to perform its intended use more safely or effectively

What is NOT an Accessory…?

"It is important to note that articles that do not meet the definition of an accessory will not be treated as accessories simply because they may be used in conjunction with a device." [FDA]

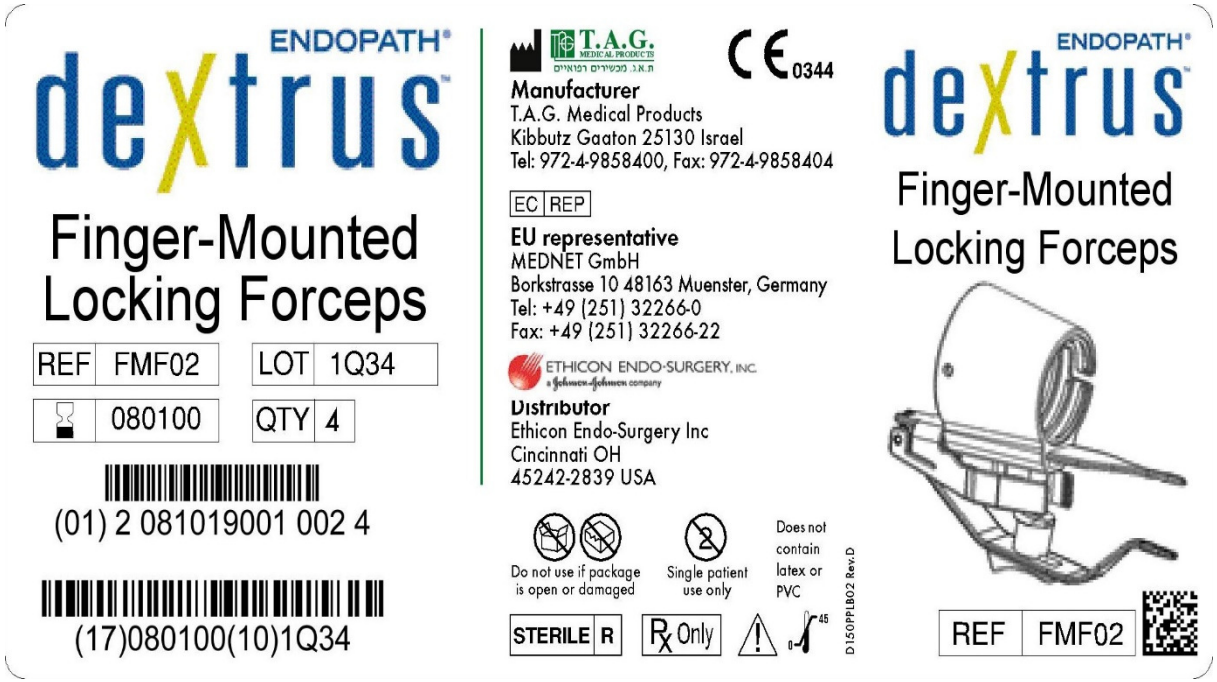
"Spare parts supplied for replacement of existing components of a device, the conformity of which has already been established, are not medical devices. If spare parts, however, change significantly the characteristics or performances of a device with regard to its already established conformity, such spare parts are to be considered as devices in their own right." [EC]

What is a Component…?

October 21, 2015 draft guidance on Manufacturing Site Change Supplements: Content and Submission amended the definition of component at 820.3(c) to include:

> "A medical device component is considered an incomplete part of the finished medical device. Additionally, ***a component is not separately distributed*** (i.e., not sold or available separately) to consumers/end users, and is only sold to the manufacturer to be incorporated into the finished medical device." [emphasis added]]

Who is responsible for UDI… the “Labeler”?



Who is the “Labeler”?

“Labeler” is 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.

1. Versus “manufacturer” or “legal manufacturer”…?
2. Who actually makes (is responsible for) what – see e.g., Complications from Metallic Tracheal Stents; Heparin recall…?
3. What will this look like in the GUDID?
4. **What will this all look like globally… will it all align?**

Stand-Alone Software (SaMD)

Need to determine if SaS is regulated as device.
Means of displaying its UDI:

- through, for example, help, about, start-up screen
- **If also packaged, needs labeled UDI too**
- Version = lot (new GS1 AI for software version)
- Major vs minor revision
- Major (new DI) – includes complex or significant changes affecting safety, intended use, performance or effectiveness.
- Minor (new PI) – generally bug fixes, usability enhancements (not safety), or security patches.

Direct Marking (DM UDI)

- In addition to the label requirement – a "permanent marking" UDI is required on the device itself if:
  "…the device is intended to be used more than once and intended to be ***reprocessed before each use***."
- DM DI can be same of different as label DI.
- Can be AIDC or HRI – or both.
- DM Exceptions part of rule – manufacturers document in DHF.

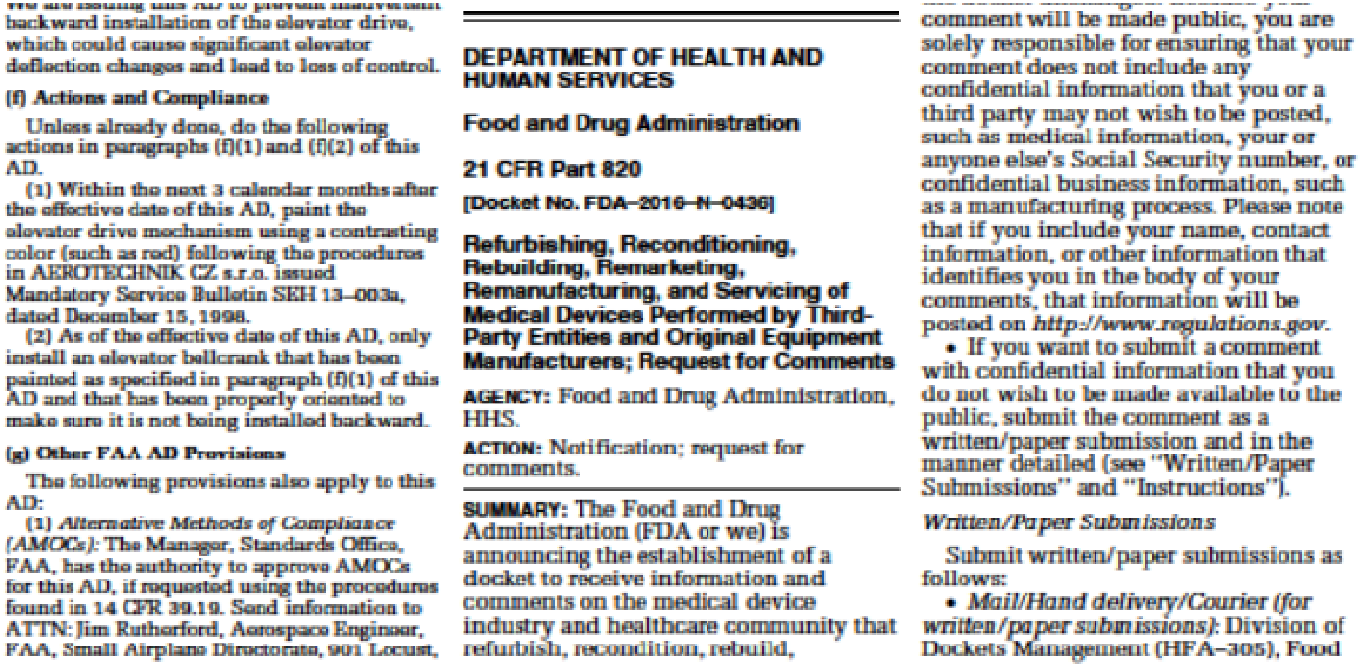
Need to understand the difference between the UDI Label and the Direct Marking requirement!

What is a Reprocessed Device…?

A reprocess device is one that is initially supplied:

- As sterile and requiring the end user to process the device after initial use (i.e., cleaning AND disinfection or sterilization) ***prior to the subsequent patient use.***
- ***For UDI DM – not cleaning alone or single patient use.***
- As non-sterile to the end user, and requiring the end user to disinfect or sterilize the initial packaged device and to subsequently reprocess the device after initial use.
- As a non-sterile SUD to the end user, and requiring the end user to sterilize the device prior to its use.

Refurbishing … Remanufacturing, and Servicing by 3rd Parties and OEMs



backward installation of the elevator drive, which could cause significant elevator deflection changes and lead to loss of control.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (f)(2) of this AD.

(1) Within the next 3 calendar months after the effective date of this AD, paint the elevator drive mechanism using a contrasting color (such as red) following the procedures in AEROTECHNIK CZ s.r.o. issued Mandatory Service Bulletin SEH 13–003a, dated December 15, 1998.

(2) As of the effective date of this AD, only install an elevator bellcrank that has been painted as specified in paragraph (f)(1) of this AD and that has been properly oriented to make sure it is not being installed backward.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust,

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 820

[Docket No. FDA–2016–N–0436]

Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive information and comments on the medical device industry and healthcare community that refurbish, recondition, rebuild,

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food

“Convenience” kits…?

UDI on kit/CP assumes that:

- Manufacturer has traceability/visibility into all of the components
- All of the components are consumed (or discarded) when opened/used

If not – then need to reconsider use of kit exception

FDA recent draft guidance proposes to modify definition to limit this exception to those kits that “… are intended to remain packaged together and ***not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user*** [emphasis added].”

- What is a collection of devices if it is not a convenience kit…?

Master Data (GUDID) Issues

- Capture, normalize and verify the GUDID attributes
- "Optional" vs conditionally required – if it is on the label – it needs to be in the GUDID (e.g., clinically relevant size, storage/handling)
- New DI Triggers
- Brand name
- Device description
- Model/version (regulatory) vs catalogue number
- Packaging hierarchy
- DUNS numbers
- Regulatory information – premarket number, Procode, GMDN PT

Barcode Verification is…

- Verification: A technical measurement process to confirm that a barcode conforms to the applicable ISO symbol specifications.

- Verifier: The tool used to make technical measurements.
  - Measures the symbols vs. standards
  - Calculates a Grade for the symbol
  - Creates an Assessment Report
  - Minimum grade is usually ‘C’ or better

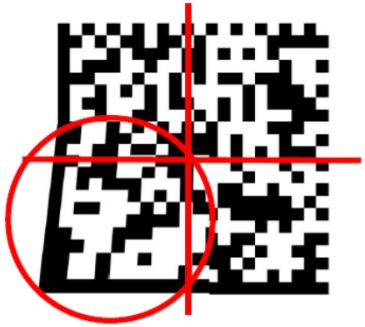


Figure 11 GS1 DataMatrix with poor Grid Non-uniformity

Figure from: GS1 2D Barcode Verification Process, Issue 1.3.21, Final, June 2014

Conforming Amendments

- 803.52 Manufacturers must include the UDI on the device label or on the device package in individual adverse event report submissions.
- 806.10 The manufacturer or importer must include on reports of corrections and removals: the UDI that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
- 806.20 Records of corrections and removals not required to be reported to FDA shall contain the UDI, or the device identifier, UPC, model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
- 814.84 The holder of an approved pre-market approval shall identify in its periodic report each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report.

Conforming Amendments

- 820.184 Device history records must include any UDI or UPC, and any other device identification(s) and control number(s) used.
- 820.198 Manufacturers must include in their complaint files any UDI or UPC, and any other device identification(s) and control number(s) used.
- 820.200 Service reports that represent an event that must be reported to FDA must include any UDI or UPC and any other device identification(s) and control number(s) used. 821.25 A manufacturer of a tracked device must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of these devices.
- 822.9 Class II and III device manufacturers required to conduct postmarket surveillance must include both premarket application/submission number and device identifiers in the postmarket surveillance plan submission.
- 820.120 Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct UDI or UPC, expiration date, control number, storage instructions, handling instructions, and any additional processing instructions.

What's Ahead? (Deadlines)

- Sep 24, 2016
  - Class II products need UDI Labeling, GUDID Submissions, Reporting
  - Class III products need Direct Marking
  - Single-use, non-sterile Implants need UDI at Point of Implantation (Labeling and GUDID Submissions were due Sep 24, 2015)
- Sep 24, 2017
  - Soft Contact Lens given a GUDID UDI Compliance extension
- Sep 24, 2018
  - Class I and all other products need UDI Labeling, GUDID Submissions, Reporting
  - Class II products need Direct Marking

Class II Compliance Date Extension – 1/3

To September 24, 2018, for certain class II devices:

1. ***Collections*** of two or more different devices packaged together in which the devices in the package are not individually labeled.

- On January 4, 2016, FDA issued "Unique Device Identification: Convenience Kits: Draft Guidance for Industry and Food and Drug Administration Staff" – **NOT yet finalized**.
- Proposes to "limit" (interpretate) the term "convenience kit" to kits that "… are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user."
- Allows each device in the kit to NOT be individually labeled with a UDI.
- This does not apply to implantable, life-sustaining or life-supporting devices.
- Final guidance will confirm definition – and what collections are if not a "convenience kit"

Class II Compliance Date Extension – 2/3

To September 24, 2018, for certain class II devices:

2. Repackaged single-use devices (SUDs):

- 21 CFR 801.30(a)(3) provides that individual single-use devices, other than implants, all of a single version or model, are not required to bear a UDI provided they are distributed together in a single device package, intended to be stored in that device package until removed for use, and not intended for individual commercial distribution.
- Extension applies to “repackaged” class II single-use devices – that are NOT individually labeled with UDI (re-packages finished devices from bulk or repackages devices made by a manufacturer into different containers).
- Single use device is intended for one use, or on a single patient during a single procedure.
- Reprocessor of Single Use Device – performs remanufacturing operations on a SUD.

Class II Compliance Date Extension – 3/3

To September 24, 2018, for certain class II devices:

3. Device constituents parts of certain combination products (CPs):

- Single entity (21 CFR 3.2(e)(1)) already covered/exempt in 801.30(b) if it has an NDC
- For “co-packaged” and “cross-labeled” ((e)(2)/(3)) CPs – which, if UDI not on CP – then each device constituent part needs its own UDI [if UDI on CP – then parts are exempt]
- CP must be assigned to CDER or CBER for premarket review and regulation
- UDI is (otherwise) required on the CP’s device constituent parts
- Not applicable to devices that are implantable, life-sustaining or life-supporting

Typical Issues – 1/2

1. SKU list incomplete
2. Assessment of accessories (vs components and service/repair/replacement parts) is incomplete or poorly documented
3. Misinterpretation/misapplication of Convenience Kit and other general exceptions
4. UDI not applied to the device's "label"
5. UDI plain text/human readable requirements not correctly met
6. Standardized date format (YYYY-MM-DD)not on all labels, regardless of UDI
7. Incorrect or incomplete interpretation of Direct Marking requirements
8. Incomplete documentation of UDI decisions (business rules)
9. "Labeler" responsibilities (private label and contract manufacturing) not well understood or documented
10. UDI Program or implementation not (easily) extensible to other needs, countries

Typical Issues – 2/2

11. UDI and GUDID SOPs or Work Instructions incomplete, poorly documented or not integrated into normal business processes
12. Barcode verification not well documented or implemented
13. Conforming amendments not appropriately updated
14. Training incomplete or poorly documented
15. Missing appropriate validation of updated/new systems
16. GUDID data missing or inaccurate and not verified
17. DUNS number management incomplete or missing
18. Lack of or poor change control process that includes UDI
19. Poor understanding and application of trigger for UDI application (commercial distribution)
20. Incorrect interpretation and application of refurbished/remanufactured devices for the purposes of UDI

Issues as we move into Class I Devices

- Visibility into entire product portfolio
- Is it even a regulated medical device (or a combination product)?
- What is retail (UPC) vs OTC?
- Is it an accessory – or “spare part” or …?
- What is its path to market?
- Is there an applicable Product code?
- Who is the “labeler”?

Summary

- UDI requires a solid foundation
- UDI is a program – not a project
- Understand what finished medical devices (and accessories and components) you distribute
- Understand who is the “labeler”
- Understand the (additional) Direct Marking requirements
- Understand barcode verification
- Understand the GUDID data elements
- Understand the conforming amendments

Questions?