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# Working Through an Effective UDI Implementation

## (Experience w/ US FDA UDI)

IMDRF Stakeholder Forum

Wednesday, 20 September 2017

**Jackie Rae Elkin, Medtronic**


GMTA is the Global Medical Technology Alliance. **Its members are national or regional medical technology associations**, which represent innovative companies that currently develop and manufacture **85 percent** of the world's medical devices, diagnostics and equipment. It **provides a forum for the development and advocacy of policies that support innovation in medical technology to address patients' healthcare needs**. Medical technologies save, support, and improve lives every day around the world.

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# Overview of Presentation

1. US FDA Commitment to an Effective Implementation (Demonstrating the Importance of Guidance)
2. Lessons Learned
3. Remaining UDI Implementation Challenges
4. Foundational Elements Needed for a Successful Implementation of UDI

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# US FDA Commitment to an Effective Implementation

The Importance of Guidance

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# Commitment to Successful UDI Implementation

- FDA has provided a **very collaborative environment** between industry and the agency to work through difficult implementation issues.
- FDA acknowledges UDI implementation **requires a learning process** as we cannot anticipation every situation given the diversity of device types, the magnitude and volume of device types.
- FDA has provided **multiple communication channels** for industry to ask questions, provide feedback, and work together.

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# FDA Collaboration Efforts with Industry

- **Many public forums dating back to 2005** for UDI education and public comment on UDI
- **Bi-annual UDI conferences led by FDA** allows industry stakeholders to learn and help educate on UDI implementation
- GUDID **training and education webinars**
- GUDID **user group sessions**
- **FDA Help Desk Service** and resources to assist industry with implementation questions

- Provided an **Exception Process for Manufacturers** to apply for exceptions and/or alternative methods for marking UDI
- Provided additional **Guidance Documents** after the publishing of the rule to address issues or challenges that arise

# UDI Guidance Provided by FDA as a Result of Collaboration and Adjudication Process

| UDI GUIDANCE DOCUMENTS ISSUED by FDA |
|---|
| **FDA UDI Alternative: UDI-A170001 –** Alternative for Existing Inventory **-** April 7, 2017 |
| **Enforcement Policy** (extension) for NHRIC and **NDC** assigned to Devices: August 30, 2016 |
| **Form and Content of Unique Device Identifier** (UDI): Draft Guidance for Industry & FDA Staff: July 25, 2016 |
| **Convenience Kits:** Draft Guidance for Industry and Food and Drug Administration Staff: January 4, 2016 |
| **Database (GUDID): Data Submission Compliance Date** of September 24, 2015 - Guidance for Industry and Food and Drug Administration Staff: August 14, 2015 |
| **Direct Marking of Devices**: Draft Guidance for Industry and Food and Drug Administration: June 26, 2015 |
| **Frequently Asked Questions, Vol. 1** - Guidance for Industry & Food and Drug Administration: August 20, 2014 |
| **Small Entity Compliance Guide**: Guidance for Industry & Food and Drug Administration Staff: August 13, 2014 |
| **Database (GUDID): Guidance** for Industry and Food and Drug Administration Staff: June 27, 2014 |
| **FDA's UDI LETTERS TO INDUSTRY** |
| **Letter of Intent to Extend Timelines** for Class I and Unclassified Devices: June 2, 2017 |
| **Extension Letter** to Rigid Gas Permeable Contact Lens Manufacturers: September 22, 2016 |
| **Extension Letter for Certain Class II** devices (kits, repackaged, combination): September 6, 2016 |
| **Availability at Implant, Extending Inventory Depletion Timelines** for Consigned Devices: March 22, 2016 |
| **Extension** Letter to Soft Contact Lens Labelers: October 6, 2015 |
| **Letter to IOL Labelers** re: GUDID Submissions: July 10, 2015 |
| **Extension Letter to Implant** (non-sterile) Labelers: November 19, 2014 |
| **Extension Letter to Class III Contact Lens** and Intraocular Lens Labelers: August 15, 2014 |
| **FUTURE GUIDANCE FOR 2017** |
| Unique Device Identification System: **Defining the Labeler** |

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# Exceptions, Alternatives & Extensions

- FDA UDI rule provides a mechanism to request exceptions, exemptions, alternatives and extensions of time for certain portions of the rule
- Enables manufactures to address implementation challenges in a positive and constructive manner

| | October 2014 | June 2015 | April 2016 | June 2017 |
|---|---|---|---|---|
| GUDID Labeler Accounts | 240 | 425 | 1275 | 4410 |
| GUDID Records | 33,000 | 75,000 | 570,000 | 1,440,277 |
| Total Helpdesk Inquiries | 4000+ | 8000+ | 16,400 | 30,836 |
| Helpdesk Closure Rate | 91% | 95% | 86% | 97.9% |

Compliments: Linda Sigg, Associate Director Informatics - FDA CDRH

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# Lessons Learned

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# FDA Letter of Intent to Extend Deadlines for Class I and Unclassified

Sent to Device Labelers - June 2, 2017

*"**With successes come challenges, and implementing UDI is no exception**. For example, after fully considering the time needed to meet UDI requirements, many labelers asked FDA for extensions to comply. In addition, we **identified complex policy and technical issues that need resolution**, such as how UDI applies to products such as medical procedure trays that contain implantable devices and instruments. **Providing accurate and timely support to labelers has also been challenging, due to the sheer number and wide diversity of devices**."*

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# Key Learnings

- Initial Implementation Timeline should be at Least 2 Years
  - IT Systems Design and Implementation
  - Device labeling must be prepared as much as one year in advance of product release
  - Numerous implementation questions required clarity from FDA, which took more than one year
- Appropriate Role of the Date of Manufacture in AIDC
  - Technical challenges
- Managing through mergers and acquisitions, as well as third party relationships (e.g. suppliers and distributors)
- Multiple to Device Identifiers (DI) assigned to one device

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# Exempt Devices Manufactured Prior to Effective Date

- UDI rules should not apply to devices manufactured or labeled prior to the rule's effective date
  - Many devices have long shelf lives
  - Healthcare systems may rely on consignment inventory

- Locating, removing, storing, and/or reworking devices after the compliance date to either re-label or destroy is unproductive and could lead to product shortage

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# Remaining Implementation Challenges

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# Capital Equipment & Accessories

- Where should the UDI label be placed?
  - Somewhere that is reasonably accessible to the user (i.e., not the underside)
- How should device accessories be labeled?
  - Accessories sold separately should be labeled with their own UDI
  - Accessories do not need a UDI when it is packaged and distributed w/ parent device (system) and the system is labeled with a UDI
  - Device components do not require a UDI

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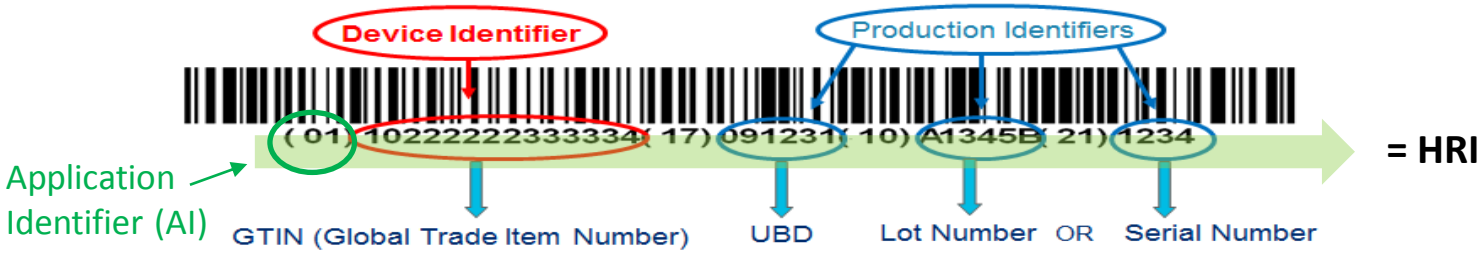
# Awareness of Standards Application

**Representation of UDI in Forms, Databases and Electronic Data Interchange (EDI)**




The Human Readable Interpretation (HRI) below the bar code is **used for the human eye to determine the information encoded in the bar code** without need to scan the barcode. The **AIs are data delimiters** and are **not** part of the data set. Therefore, the **AIs should not be displayed in forms, electronic data interchange (EDI), electronic systems and databases as part of the data-set.**

**Proposed Solution :** Separate discrete fields for each element of the UDI.

- **Device Identifier**: 1022222222333334
- **Use By Date:** 091231
- **Lot Number:** A1345B
- **Serial Number:** 1234

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# Labeling for Procedure Sets and Trays

- Background: Non-sterile orthopedic sets and trays may contain hundreds of devices in a small space, making the labeling very difficult or impossible
  - FDA provided an initial compliance date extension for implantable devices so that labeling approaches could be developed
- FDA has taken a flexible approach
  - Permit cross reference tools
  - Permit DI only when technologically infeasible

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# Establishing Responsibility

Providing clear definition of the entity responsible for UDI is critically important

"Labeler"

"Manufacturer"

It is imperative that responsibility for creating and maintaining the UDI is established early and roles and responsibilities are clearly understood.

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# Needed for Effective UDI Implementation

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# General Consideration to Facilitate an Effective UDI Implementation

- ☑ Implementation Schedule
- ☑ Specification Availability
  - **Reference Table for UDI Data Elements:** (data type, structure, LOV, editing rules, conditional fields, cardinality rules … → *see FDA GUDID data reference table*
  - **UDI Data Exchange Instructions:** messaging structure, XML schema, content, vocabulary, validation rules …… → *see FDA HL7/SPL Implementation Specification.*
    - ✓ *Consider other data exchange options available, e.g., .xls upload, XML messaging standards for batch upload*
- ☑ Implementation Support
- ☑ UDI Adjudication Process for Issues & Requests for Alternatives.
- ☑ Guidance documents are timely

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# Closing Thought

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# UDI

**If we wait until we know everything, we will never start ……**

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# THANK YOU!

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