FDA Hot Topics:
Update on Medical Device Guidances

Unique Device Identification and the Global Unique Device Identification Database
UDI & GUDID

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What is UDI?
What my doctor thinks it is.
What Supply Chain Thinks it is
What the CEO Thinks it is…
What it really is

System intended to...

* Decrease Medical Errors

* More Rapid Identification of Medical Devices with Adverse Events

* Facilitate Recalls

* Easily Accessible Source of Definitive Device Identification Information

* Better-Focused and More Effective Safety Communication

* Encourage cost effectiveness by improving delivery and supply chain efficiency
FDA’s UDI General Rule

• EVERY medical device label MUST have a UDI.

• EVERY device package MUST have a UDI.

• …BUT there are EXCEPTIONS

• What is a label?  § 201(k) Display of written, printed, graphic matter upon immediate container of any article.
Exceptions

- SUD packaging
- Existing inventory
- Custom
- Investigational
- Veterinary
- Export-only

- Research only
- National stockpile
- Class I doesn’t need PI
- Class I GMP exempt (527 product codes)
Not just one new regulation

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
UDI has two parts

1. Device Identifier (DI)
   - Mandatory
   - Static
   - Identifies specific device version or model
   - Identifies labeler
UDI has two parts

1. Production Identifier (PI)
   
   Conditional
   
   Variable
   
   Identifies specific details of individual device
   
   1. lot or batch number
   2. serial number
   3. expiration date
   4. date of device’s manufacture
Example label with UDI
(courtesy of Jay Crowley and BSI Standards Limited)

Date Format = YYYY-MM-DD

Device Identifier

Production Identifiers
Issuing Agencies

gs1.org  Nonprofit design and implement global standards and solutions

hibcc.org  Health Industry Business Communications Council nonprofit standards development

ICCBBA  Enhances safety for patients by managing and promoting the ISBT 128 international information standard for use in transfusion and transplantation.
When do you need a new DI?

- New version or model
- New device package
Compliance Dates
September 24

Implementation (compliance) timeframes:
– Year 1: class III and devices licensed under PHS Act
– Year 2: class II/I implants and devices that are lifesupporting/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.
Standardized Date Format

- IF the label has a date
  - YYYY-MM-DD
  - Must include day
  - Compliance dates apply
  - If not subject to UDI, compliance date is year 5
Definition of a Labeler

• Any person who causes a label to be
• APPLIED to a device
• REPLACED or MODIFIED on a device
• WITH the INTENT device will be COMMERCIALLY DISTRIBUTED

Just adding distributor name and contact information?
• Not a labeler.
Direct Part Marking

- NOT REQUIRED for IMPLANTABLES!!!!
- REQUIRED for devices that are
  - intended to be used more than once
  - AND
  - reprocessed (cleaned, disinfected, sterilized)
- REQUIRED for STAND-ALONE SOFTWARE
- Direct UDI can be identical or different from label UDI
- EITHER plain text OR AIDC
- OR both plain text and AIDC
Exceptions to Direct Part Marking

• Interferes with safety or effectiveness
• Not technologically feasible

• NOTE exception decision with rationale in design history file
Technical Tasks

- Utilize data with HL7 SPL
- Contact Issuing Agency of Choice for your company prefix.
- Develop working spreadsheet with all devices, labeler, compliance date, levels of packaging, GUDID information
- Assign identification information to devices
- Work with issuing agency to identify, study, and implement standards.
## Example of GUDID data

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Description</th>
<th>Data Entry Notes</th>
<th>Edit Rules After Grace Period</th>
<th>Required in Database?</th>
<th>Data Type &amp; Length</th>
<th>Entry List of Values (LOV)</th>
<th>New DI Trigger</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity per Package</td>
<td>The number of packages with the same Primary DI or Package DI within a given packaging configuration. The quantity of a package configuration must be &gt;1. Examples: Package – Carton, Pkg DI 201 contains 4 boxes of DI 101; the quantity per package is 4. Package – Case, Pkg DI 301 contains 5 cartons of Pkg DI 201; the quantity per package is 5. Package – Carton, Pkg DI 202 contains</td>
<td>Enter the number of devices per package.</td>
<td>Add</td>
<td>Conditionally Required*</td>
<td>Type: Num. Length: 9</td>
<td>NA</td>
<td>no</td>
</tr>
</tbody>
</table>
What data goes into GUDID?

- Package DI Number
- Contains DI Package
- Package Type
- Package Discontinue Date
- Package Status
What data goes into GUDID?

- Issuing Agency
- Primary DI Number
- Unit of Use DI Number
- Labeler DUNS Number
- Company Name
- Brand Name
- Version or Model
What data goes into GUDID?

• Device Description
• DI Record Publish Date (YYYY-MM-DD)
• Commercial Distribution End Date
• Commercial Distribution Status
• MRI Safety Status
What data goes into GUDID?

- Customer Contact Phone
- Customer Contact Email
- Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)
- Kit
- Combination Product
- Device Exempt from Premarket Submission
What data goes into GUDID?

- Lot or Batch Number
- Manufacturing Date
- Serial Number
- Expiration Date
- Donation Identification Number
- Latex information
- Prescription or OTC
What data goes into GUDID for Direct Marking?

- Device Subject to Direct Marking (DM) but Exempt
- DM DI Different from Primary DI
- DM DI Number
What data goes into GUDID if you have a Secondary DI?

• Issuing Agency
• Secondary DI Number
What data goes into GUDID?

• Size Value
• Size Unit of Measure
• Storage and Handling Type
• High Value
• Unit of Measure
• Device Packaged as Sterile
• Requires Sterilization Prior to Use
• Sterilization Method
What data goes into GUDID?

- FDA Premarket Submission Number
- Product Code
- Product Code Name
- FDA Listing Number
- GMDN Code
- GMDN Name
- For Single-Use
GUDID Inputs -- GMDN

- GMDN Codes will be available at no cost

- Obtain GMDN PT codes -- GMDN Agency

- Future GUDID toll will enable users to select a GMDN preferred term to be used in their GUDID submission until a GMDN PT code can be obtained from the GMDN Agency.
UDI around the world

IMDRF UDI Working Group Guidance 09 December 2013

Differences between FDA Final Rule and EU approach

- Classification systems
- EU regulatory distinction between medical devices and in vitro diagnostics
- Timing
- Databases – GUDID vs. EUDAMED
Organizational implementation

- Officially determine your company workflow and assignment of UDI responsibilities.
- Write and revise SOPs. Train and communicate.
- Understand device distribution patterns and labeler responsibilities with business partners.
Key resources

• FDA final rule

• FDA GUDID guidance, June 27, 2014
Questions?
Thank You!

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