DI Record

March 10, 2016

Indira R Konduri
GUDID Program Manager
Informatics Staff
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Learning Objectives

- Obtain an overview of GUDID
- Understand the DI record and the data elements
- Understand how to manage your DI record so the information is current
- Learn about best practices for better GUDID data
UDI = DI + PI

Device Identifier(DI) = mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device

Production Identifier(PI) = a conditional, variable portion of a UDI that identifies one or more of the following when included in the UDI:
Lot or batch number, Serial number, Expiration date, Manufacturing date, and, for an HCT/P regulated as a device, the distinct identification code
Repository of key device identification information

Contains ONLY the DI; PIs are not submitted to nor stored in the GUDID

Contains only PI flags to indicate which PIs are on the device UDI
GUDID Overview

Labelers - GUDID Submission Options

GUDID HL7 SPL Submission

FDA ESG

FDA Electronic Submissions Gateway

GUDID Web Interface

Public Users - GUDID Search & Retrieval Options

Search

Download

Web Services

GUDID

Global Unique Device Identification Database

Public Users

accessgudid.nlm.nih.gov
GUDID Web Interface

• Secure Web Application

• Submission of device information one record at a time by Labelers

• Suitable for those with small submission volumes
DI Record and Data Elements
Device Identifier Record

• A Device Identifier (DI) identifies –
  – A given version or model of a device AND
  – The Labeler of the device

• DI Record in GUDID
  – Device Identifier + GUDID Data Element values
The majority of the DI record information is on the device label.
GUDID DI Record

- Web Interface – created by LDE users
- HL7 SPL Submission option – submitted as xml files
Primary DI = DI on the base package. Base Package is the lowest package level containing a full UDI.
Labeler DUNS Number

The company name and address associated to the Labeler DUNS Number should match the company name and address on the device label. A Doing Business As (DBA) name is also acceptable.
Labeler DUNS and the GUDID DI Record

DI record Company Name and Address is associated to the Labeler DUNS Number
Labeler DUNS and the AccessGUDID DI Record

DI record Company Name associated to the Labeler DUNS Number
### Device Information

**Direct Marking (DM)**

- [ ] Device Subject to Direct Marking (DM), but Exempt
- [ ] DM DI Different from Primary DI

**DM DI Number:**

**Secondary DI**

<table>
<thead>
<tr>
<th>Issuing Agency</th>
<th>Secondary DI Number</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>GS1</td>
<td>00009090909090</td>
<td></td>
</tr>
</tbody>
</table>

**Package DI**

<table>
<thead>
<tr>
<th>Package DI Number</th>
<th>Quantity per Package</th>
<th>Contains DI Package</th>
<th>Package Type</th>
<th>Package Discontinue Date</th>
<th>Package Status</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>wsPkg2</td>
<td>10</td>
<td>wsPkg1</td>
<td>Carton</td>
<td></td>
<td>In Commercial Distribution</td>
<td></td>
</tr>
<tr>
<td>wsPkg1</td>
<td>5</td>
<td>wsDIOverview</td>
<td>Box</td>
<td></td>
<td>In Commercial Distribution</td>
<td></td>
</tr>
</tbody>
</table>

**Customer Contact**

<table>
<thead>
<tr>
<th>Customer Contact Phone</th>
<th>Customer Contact Email</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>8005551234</td>
<td><a href="mailto:xxx@xx.xx">xxx@xx.xx</a></td>
<td></td>
</tr>
<tr>
<td>99999999999</td>
<td><a href="mailto:none@none.net">none@none.net</a></td>
<td></td>
</tr>
</tbody>
</table>
Levels of Packaging

Package Configurations of the Base Package

**Base Package**

*Primary DI = 1001*

- **Base Package** is the lowest level of a medical device package containing a full UDI

**Package DI = 2001**

- Catheter, 12 Fr, Box of 30
- Contains 30 units of
- Base Package DI 1001
- Quantity per package = 30

**Package DI = 2002**

- Catheter, 12 Fr, Box of 50
- Contains 50 units of
- Base Package DI 1001
- Quantity per package = 50

**Package DI = 3001**

- Catheter, 12 Fr, Case of 360
- Contains 12 units of
- Package DI 2001
- Quantity per package = 12
Packages in GUDID

Primary DI = base package DI

Higher level Package DIs for a given version or model are entered as part of the same DI record. Please DO NOT enter separate DI records for higher level packages.
### Device Status

- **Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)**
- **Kit**
- **Combination Product**

#### Premarket

- **Device Exempt from Premarket Submission**

<table>
<thead>
<tr>
<th>FDA Premarket Submission Number</th>
<th>Supplement Number</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>P100001</td>
<td>000</td>
<td></td>
</tr>
<tr>
<td>BK000030</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

#### FDA Product Code

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Code Name</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>UZ</td>
<td>OI, Clearing</td>
<td></td>
</tr>
</tbody>
</table>

#### FDA Listing

- **GMDN**

<table>
<thead>
<tr>
<th>FDA Listing Number</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>D202923</td>
<td></td>
</tr>
</tbody>
</table>

#### GMDN

<table>
<thead>
<tr>
<th>Code</th>
<th>Name</th>
<th>Definition</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>99999</td>
<td>FOR TESTING PURPOSES ONLY</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GMDN

• GMDN = Global Medical Device Nomenclature
• Provides a way to group or categorize devices
• Consists of:
  – GMDN Code
  – GMDN Preferred Term
  – GMDN Preferred Term Definition
• Required element in GUDID
## Device Characteristics

### For Single-Use
- *Yes*

### Production Identifier(s) on Label
- **Lot or Batch Number:** *Yes*
- **Serial Number:** *No*
- **Expiration Date:** *Yes*
- **Manufacturing Date:** *No*
- **Donation Identification Number:** *No*

### Prescription Status
- **Prescription Use (Rx)**
- **Over the Counter (OTC)**

### Latex Information
- Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437): *
- □ Device labeled as "Not made with natural rubber latex"

### MRI Safety
- **What MRI safety information does the labeling contain?:** *
  - Labeling does not contain MRI Safety Information
  - MR Safe
  - MR Unsafe
  - MR Conditional
  - Labeling does not contain MRI Safety Information
### Device Characteristics

#### Clinically Relevant Size

<table>
<thead>
<tr>
<th>Size Type Text</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth: 2.5 Centimeter</td>
<td></td>
</tr>
<tr>
<td>Length: 3.5678999000 Femtometer</td>
<td></td>
</tr>
</tbody>
</table>

#### Storage and Handling

<table>
<thead>
<tr>
<th>Storage and Handling</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling Environment Temperature: greater than 56 Degrees Celsius</td>
<td></td>
</tr>
<tr>
<td>Handling Environment Temperature: greater than 45 Degrees Fahrenheit</td>
<td></td>
</tr>
<tr>
<td>Handling Environment Temperature: exactly 45 Degrees Celsius</td>
<td></td>
</tr>
<tr>
<td>Storage Environment Humidity: between 45 and 75 Percent (%) Relative Humidity</td>
<td></td>
</tr>
</tbody>
</table>

#### Sterilization

| Device Packaged as Sterile: *                | No     |
| Requires Sterilization Prior to Use: *      | Yes    |

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sound Waves</td>
<td></td>
</tr>
</tbody>
</table>
DI Record Management
DI Record Life Cycle

• Managing entry and edits to device identification information throughout the life of the device

• 3 DI record states –
  – Draft
  – Unpublished
  – Published
Draft DI Record

- Use to “test/learn” GUDID
- Saved in the system, but not “submitted”
- Unlimited editing
- Purged after 180 days of inactivity
- Allows for Review prior to submitting

Review checks record against business rules
Draft DI Record- Review Failed

There were error(s) found while processing your request.

Cannot Submit a record with errors
Fix errors and click Review or re-Save Draft
Draft DI Record - Review Passed

Review Passed! May submit record!
Submit Or re-Save Draft
Submitted DI Record

• No longer in DRAFT state – time to pay attention to GUDID business rules!

• Publish Date determines DI record state -- Unpublished OR Published
DI Record Publish Date

• Determines when a DI record is saved in the “published” state

• GUDID requires Publish Date to be today or in the future.

• GUDID submission requirements are met the date the DI record is saved in the “published” state
Moving between DI Record States

- Draft
  - Business rules pass
  - Publish Date in future
  - Submit

- Unpublished
  - Nightly automated check
  - If Publish Date = today

- Published
  - Business rules pass
  - Publish Date is today
  - Submit
Unpublished DI Record

• DI record has passed review
• DI record was submitted
• Publish Date in the future
• Unlimited editing
• Records are NOT released to AccessGUDID
• Can be copied to create new DI records
Unpublished DI Record is a Submitted DI record with a future Publish Date.
Record will move to “Published” state on the set Publish Date.
Moving between DI Record States

- **Draft**
  - Business rules pass
  - Publish Date in future
  - Submit

- **Unpublished**
  - Nightly automated check
  - If Publish Date is today

- **Published**
  - Business rules pass
  - Publish Date is today
Published DI Record

- DI record has passed review
- DI record was submitted
- Publish Date is today OR in the past
- Limited editing
- Records are released to AccessGUDID
- Can be copied to create new DI records
- GUDID submission requirements are met the date the DI record is saved in the “published” state
**Published DI Record**

### Device Information

<table>
<thead>
<tr>
<th>Device Identifier (DI) Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Issuing Agency: <strong>HIBCC</strong></td>
<td>Primary DI Number: <strong>PUBLISHEDEXAMPLE</strong></td>
</tr>
<tr>
<td>Labeler DUNS Number: 039169488</td>
<td>Company Name: Safeway Grocery</td>
</tr>
<tr>
<td>Company Physical Address: 4551 Forbes Blvd, Lanham, MD 20706-4389</td>
<td></td>
</tr>
</tbody>
</table>

#### Commercial Distribution

- **DI Record Publish Date (yyyy-mm-dd):** 2014-07-19
- **Commercial Distribution Status:** In Commercial Distribution

**DI Record Publish Date in the past**
DI Record Life Cycle

- DI Record Life Cycle = DI record states + business rules
- DI record state determines applicable business rule

**Draft DI Record**
- Business rules N/A
- Publish Date N/A
- Unlimited Editing
- Not released to AccessGUDID
- Not available via HL7 SPL

**Unpublished DI Record**
- Business rules passed
- Publish Date in future
- Unlimited Editing
- May be copied
- Not released to AccessGUDID

**Published DI Record**
- Business rules passed
- Publish Date is today or in future
- Limited Editing
- May be copied
- Released to AccessGUDID
DI Record Management
Editing Published DI records
New DI Trigger Element – when changed, requires a new DI and new DI record in GUDID.

<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>For Single-Use</td>
<td>Indicates that the device is intended for one use or on a single patient during a single procedure.</td>
<td>Choose Yes/No from the drop down list.</td>
<td>None</td>
<td>Required</td>
<td>Type: Boolean</td>
<td>Yes/No</td>
<td>YES</td>
</tr>
<tr>
<td>Device Packaged as Sterile</td>
<td>Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.</td>
<td>Choose Yes/No from the drop down list. The two Sterilization Method questions are independent of each other; this element is designed to capture information about the device as it enters Commercial Distribution. These data elements are not designed to capture sterilization procedures executed by the manufacturer or labeler.</td>
<td>None</td>
<td>Required</td>
<td>Type: Boolean</td>
<td>Yes/No</td>
<td>YES</td>
</tr>
</tbody>
</table>
# Grace Period Applies to Published DI Records

<table>
<thead>
<tr>
<th>Publish Date</th>
<th>Grace Period Start Date</th>
<th>Grace Period End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Friday, January 15, 2016</td>
<td>Saturday, January 16, 2016</td>
<td>Monday, February 15, 2016</td>
</tr>
</tbody>
</table>

Grace Period = 30 calendar days*

During Grace Period
- Unlimited Editing, except for Publish Date
- **Please review your data in GUDID!**

After Grace Period
- **Record released to AccessGUDID**
- New DI Trigger Data Elements – no edits
- Limited Editing

*Grace period subject to change
GUDID and Data Quality

• Start with GOOD Data

• Review your data in GUDID During-the-Grace-Period
  – Export your records from GUDID and review/validate

• Do not wait to do your review after records show up on AccessGUDID, which is AFTER the grace period when editing is limited
# Best Practices for Better Data

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Data Quality Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Identifier</td>
<td>Ensure your DI is correct – validate your check digits</td>
</tr>
<tr>
<td>Version or Model</td>
<td>Do not include the word “Model” or “Version”</td>
</tr>
<tr>
<td></td>
<td>If no Version or Model available, enter Catalog Number</td>
</tr>
<tr>
<td>Device Description</td>
<td>Do not leave blank; recommend approved/cleared indications for use</td>
</tr>
<tr>
<td>Clinically Relevant Size</td>
<td>Do not include size under ‘Device Description’ or ‘Brand Name’</td>
</tr>
<tr>
<td></td>
<td>Use List of Values vs. “Device Size Text, Specify”</td>
</tr>
<tr>
<td>GMDN Code</td>
<td>One code sufficient for most medical devices</td>
</tr>
<tr>
<td>Donation Identification Number (DIN)</td>
<td>Applicable to ICCBBA Device Identifiers ONLY</td>
</tr>
</tbody>
</table>
Steps for Success!

1) Review resources on the UDI Website
2) Select Issuing Agency and label your devices with UDI
3) Determine primary submission option
4) Gather your data
5) Understand the GUDID Account Structure
6) Identify/Obtain DUNS numbers
7) Obtain a GUDID Account
8) Submit DI records
9) Subscribe to get notified about GUDID System Status
GUDID System Status

• Subscribe to GUDID Email Alerts by visiting our website

• Scheduled downtimes -- email alerts sent and posted on www.fda.gov/udi

• Unscheduled downtimes
  – Visit www.fda.gov/udi for information
  – If no information, report issue via FDA UDI Help Desk
Your Call to Action

• It is time to get started!
• Utilize the resources available on our website
• Do not forget data quality
• Be sure to understand the DI record edit rules
• Use the grace period effectively to ensure your device information is accurate
• Subscribe to the GUDID System Status notification
Providing Industry Education

1. CDRH Learn – Multi-Media Industry Education
   - over 80 modules - videos, audio recordings, power point presentations, software-based “how to” modules
   - accessible on your portable devices: http://www.fda.gov/Training/CDRHLearn

2. Device Advice – Text-Based Education
   - comprehensive regulatory information on premarket and postmarket topics: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. Division of Industry and Consumer Education (DICE)
   - If you have a question - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Live Agents 9am – 12:30 pm; 1-4:30 pm EST)
   - Web Homepage: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm