UDI - Experiences, Challenges and Keys to Success

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Statutes and Regulation

- FDA Amendments Act, 2007
- FDA Safety and Innovation Act, 2012
- UDI Rule, September 24, 2013

Link: UDI Final Rule
Objectives of the UDI Program

Establish a system to adequately identify devices through distribution and use

- Facilitate the rapid and accurate identification of a device
- Enable access to important information concerning the device
- Provide a standard and clear way to document device use in electronic health records, clinical information systems, and registries
What is a UDI?

Found on the device label, packaging or, in some cases, on the device itself

Both in plain text and machine readable format (AIDC)

UDI = DI + PI
## Compliance Dates for UDI Requirements

<table>
<thead>
<tr>
<th>Device</th>
<th>Label/GUIDID/Date Format</th>
<th>Direct Mark (When Required)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class III (including class III LS/LS)</td>
<td>September 24, 2014</td>
<td>Class III LS/LS devices must bear a permanent UDI by September 24, 2015 and all other class III devices must bear a permanent UDI by September 24, 2016</td>
</tr>
<tr>
<td>Devices licensed under the PHS Act</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implantable (class II, class I &amp; unclassified)</td>
<td>September 24, 2015</td>
<td>N/A</td>
</tr>
<tr>
<td>LS/LS (class II, class I &amp; unclassified)</td>
<td>September 24, 2015</td>
<td>September 24, 2015</td>
</tr>
<tr>
<td>Class II (other than I/LS/LS)</td>
<td>September 24, 2016</td>
<td>September 24, 2018</td>
</tr>
<tr>
<td>Class I or unclassified (other than I/LS/LS)</td>
<td>September 24, 2018</td>
<td>September 24, 2020</td>
</tr>
</tbody>
</table>

[Link: Details on Compliance Dates](#)
Record Counts to Date

GUDID Records

- Almost 34,000 on September 24, 2014
- Over 49,000 as of today

Helpdesk Cases

- Almost 4,000 on September 24, 2014 with a 90% closure rate
- Over 6,000 as of today with a 95% closure rate
Solving Challenges

Versions and models of devices
- Very general definition of version or model
- Helps to see the data

Heterogeneity of devices
- Wide variety of characteristics
- Implantables, instruments, orthopedic trays, software, etc.

Education and outreach
- Need to understand the landscape
- Helps to tailor the message to the audience

Link: UDI Website
Questions?

FDA UDI Website:
www.fda.gov/udi

Slide Presentations, Transcripts and Webinar Recordings are available at:
www.fda.gov/CDRHWebinar
Under Heading: Unique Device Identification (UDI) System
General Advice

- Labelers: Educate yourselves and work with agency
- Do not wait, there are things you can do to prepare
- Agency: Staffing, preparation and collaboration are key
- Know your data, and make sure you have good data quality
What’s next?

- AccessGUDID public release of GUDID data
- Convenience Kit Guidance
- Direct Mark Guidance
- Frequently Asked Questions, Volume 2
- Upcoming compliance dates
Key Benefits of UDI

1. Improve Patient Safety
2. More Accurate Understanding of Device Benefit-Risk Profile
3. Facilitate Device Innovation and Patient Access

Strengthening our National System for Medical Device Postmarket Surveillance