November 19, 2014

Dear Implant Labelers:

Effective immediately, the FDA’s Center for Devices and Radiological Health (CDRH) is granting an extension of the compliance date for the Unique Device Identification System labeling requirements to September 24, 2016, for medical devices that meet all of the following criteria: (1) classified with primary product codes and regulations listed below, (2) single use implants, and (3) intended to be sterilized (or cleaned and sterilized) before use. Most of the devices that meet these three criteria are supplied non-sterile by the manufacturer. Additional background and the conditions that apply to this compliance date extension are summarized below.

**Background:**
On September 24, 2013, the FDA published a [final rule establishing a unique device identification system](https://www.fda.gov/RegulatoryInformation/LawsRegulationsGuidance/Regulations/62213U46220.html), 78 FR 58786 (the UDI Rule). The UDI Rule outlines labeling, data submission and standard date formatting requirements for all medical devices in commercial distribution in the United States, unless an exception or alternative applies. Implementation of the Unique Device Identification System is phased in based on [compliance dates established by FDA](https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm279380.htm). The compliance date for class III devices, including class III implants, was September 24, 2014. The compliance date for implantable devices that are Class I, Class II or unclassified is September 24, 2015.

The goal of the UDI Rule is to establish a system for the adequate identification of medical devices through their distribution and use, via the entire supply chain to point of use with patients. The proposed UDI Rule contained a provision requiring implantable devices to be directly marked with a unique device identifier to ensure adequate identification of such devices even if separated from their labels. This proposal was not finalized in the UDI Rule because it was presumed that implants would be accompanied by their unique device identifier (UDI) label or package with UDI label up to the point of implantation. Implementation of this requirement, with the accompanying expectation that providers would incorporate UDIs into patient health records, patient implant cards, electronic health records (EHRs) and personal health records (PHRs), was thought to provide the ability to adequately identify an implantable device. This is not the case, however, for implants (generally supplied non-sterile) that are cleaned and sterilized prior to use because such devices are separated from their original label and packaging in order to undergo cleaning and sterilization.

In August 2014, Advanced Medical Technology Association (AdvaMed), on behalf of the manufacturers in their Orthopedic Sector, [presented a proposal to FDA](https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm279380.htm) that describes the unique complexities and challenges for conveying UDIs on the device or device label to the point of use for products such as orthopedic implant sets used in various types of spine, trauma, craniomaxillofacial, or extremity surgeries. AdvaMed also outlined potential solutions to ensure the adequate identification of devices separated from their original label and package during
cleaning and sterilization by making the UDI available to be recorded at the point of use. AdvaMed noted that in many cases, additional work (e.g., development, testing, validation, FDA clearances/approvals as needed, and facilitating adoption by the health care community) needs to be done in order to both develop and implement such solutions, while assuring that these solutions do not interfere with healthcare delivery.

**UDI Compliance Date Extension Specifications and Conditions:**
Pursuant to 21 CFR 801.55(c) and for the reasons stated above, FDA is initiating extensions to the compliance date for UDI labeling requirements to medical devices that are:

1. classified with primary product codes and regulations listed below,
2. single use implants, and
3. intended to be sterilized (or cleaned and sterilized) before use.

FDA is initiating this extension to allow time for the development and implementation of an alternative that would provide for more accurate and precise device identification than the requirements of 21 CFR 801 subpart B.

<table>
<thead>
<tr>
<th>Device</th>
<th>Product Code</th>
<th>Classification Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant, endosseous, root-form, abutment</td>
<td>NHA</td>
<td>21 CFR 872.3630</td>
</tr>
<tr>
<td>Implant, endosseous, orthodontic</td>
<td>OAT</td>
<td>21 CFR 872.3640</td>
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<tr>
<td>Lock, wire, and ligature, intraoral</td>
<td>DYX</td>
<td>21 CFR 872.4600</td>
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<tr>
<td>External mandibular fixator and/or distractor</td>
<td>MQN</td>
<td>21 CFR 872.4760</td>
</tr>
<tr>
<td>Plate, bone</td>
<td>JFY</td>
<td></td>
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<tr>
<td>Prosthesis, condyle, mandibular, temporary</td>
<td>NEI</td>
<td>21 CFR 872.4770</td>
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<tr>
<td>Screw, fixation, intraosseous</td>
<td>DZL</td>
<td>21 CFR 872.4880</td>
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<tr>
<td>Mesh, surgical, metal</td>
<td>EZX</td>
<td>21 CFR 878.3300</td>
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<tr>
<td>Clip, aneurysm</td>
<td>HCH</td>
<td>21 CFR 882.5200</td>
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<tr>
<td>Cover, burr hole</td>
<td>GXR</td>
<td>21 CFR 882.5250</td>
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<tr>
<td>Plate, cranioplasty, preformed, alterable</td>
<td>GWO</td>
<td>21 CFR 882.5320</td>
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<tr>
<td>Plate, cranioplasty, preformed, non-alterable</td>
<td>GXN</td>
<td>21 CFR 882.5330</td>
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<tr>
<td>Fastener, plate, cranioplasty</td>
<td>HBW</td>
<td>21 CFR 882.5360</td>
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<tr>
<td>Shunt, central nervous system and components</td>
<td>JXG</td>
<td>21 CFR 882.5550</td>
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<tr>
<td>Bone fixation cerclage, sublaminar</td>
<td>OWI</td>
<td>21 CFR 888.3010</td>
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<tr>
<td>Cerclage, fixation</td>
<td>JDQ</td>
<td></td>
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<tr>
<td>Rod, fixation, intramedullary and accessories</td>
<td>HSB</td>
<td>21 CFR 888.3020</td>
</tr>
<tr>
<td>Appliance, fixation, nail/blade/plate combination, multiple component</td>
<td>KTT</td>
<td>21 CFR 888.3030</td>
</tr>
</tbody>
</table>
### Devices included in the labeling compliance date extension, if such devices are also single use implants intended to be sterilized before use

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<tr>
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<tr>
<td>Appliance, fixation, nail/blade/plate combination, multiple component, metal composite</td>
<td>LXT</td>
<td>21 CFR 888.3030</td>
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<tr>
<td>Appliance, fixation, nail/blade/plate combination, single component</td>
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<td>Condylar plate fixation implant</td>
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<td>Device, fixation, proximal femoral, implant</td>
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<tr>
<td>Nail, fixation, bone</td>
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<tr>
<td>Plate, Fixation, Bone</td>
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<td>Staple, fixation, bone</td>
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<td>Washer, bolt nut</td>
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<td>Component, traction, invasive</td>
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<td>Fastener, fixation, nondegradable, soft tissue</td>
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<td>Pin, fixation, smooth</td>
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<tr>
<td>Pin, fixation, threaded</td>
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<tr>
<td>Sacroiliac joint fixation</td>
<td>OUR</td>
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<tr>
<td>Screw, Fixation, Bone</td>
<td>HWC</td>
<td></td>
</tr>
<tr>
<td>Accessories, Fixation, Spinal Interlamina</td>
<td>LYP</td>
<td></td>
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<td>KWP</td>
<td>21 CFR 888.3050</td>
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<td>Orthosis, spine, plate, laminoplasty, metal</td>
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<tr>
<td>Spinous process plate</td>
<td>PEK</td>
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<tr>
<td>Anterior staple as supplemental fixation for fusion</td>
<td>PHQ</td>
<td>21 CFR 888.3060</td>
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<tr>
<td>Appliance, Fixation, Spinal Intervertebral Body</td>
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<tr>
<td>Implant, fixation device, spinal</td>
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<tr>
<td>Spinal vertebra body replacement device</td>
<td>MQP</td>
<td></td>
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<tr>
<td>Orthosis, spinal pedicle fixation</td>
<td>MNI</td>
<td>21 CFR 888.3070</td>
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<tr>
<td>Orthosis, spinal pedicle fixation, for degenerative disc disease</td>
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<tr>
<td>Orthosis, spondylolisthesis spinal fixation</td>
<td>MNH</td>
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<tr>
<td>Pedicle screw spinal system, adolescent idiopathic scoliosis</td>
<td>OSH</td>
<td>21 CFR 888.3080</td>
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<td>Posterior metal/polymer spinal system, fusion</td>
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<tr>
<td>Intervertebral fusion device with bone graft, cervical</td>
<td>ODP</td>
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<tr>
<td>Intervertebral fusion device with bone graft, lumbar</td>
<td>MAX</td>
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</tbody>
</table>
Therefore, FDA is extending the compliance date of UDI labeling requirements under 21 CFR 801 subpart B and the format of dates on the device label requirement under 21 CFR 801.18 to September 24, 2016, for all classes of medical devices that meet all three of the criteria specified above. The additional time provided by this extension is intended to allow the affected labelers to develop and implement approaches that will help ensure that the UDI is available at the point of use. Some affected labelers may have already implemented the UDI label and date format requirements for these devices. In such cases, this extension would only apply to the requirement to convey the UDI to point of use/implantation.

The compliance dates for the requirement to submit information to the Global Unique Device Identification Database (GUDID) under 21 CFR 830 subpart E are not extended; these compliance dates remain September 24, 2014, for class III devices and September 24, 2015, for implantable devices that are Class II, Class I or unclassified.

For additional information, please contact the FDA UDI Help Desk.

Sincerely yours,

Thomas P. Gross -S

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Center for Devices and Radiological Health
Food and Drug Administration