DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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. 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. 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 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.

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

Devices included in the labeling compliance date extension, if such devices are also single use implants intended to be sterilized before use		
Device	**Product Code**	**Classification Regulation**
Appliance, fixation, nail/blade/plate combination, multiple component, metal composite	LXT	21 CFR 888.3030
Appliance, fixation, nail/blade/plate combination, single component	KTW	
Condylar plate fixation implant	JDP	
Device, fixation, proximal femoral, implant	JDO	
Nail, fixation, bone	JDS	
Plate, Fixation, Bone	HRS	
Staple, fixation, bone	JDR	
Washer, bolt nut	HTN	
Component, traction, invasive	JEC	21 CFR 888.3040
Fastener, fixation, nondegradable, soft tissue	MBI	
Pin, fixation, smooth	HTY	
Pin, fixation, threaded	JDW	
Sacroiliac joint fixation	OUR	
Screw, Fixation, Bone	HWC	
Accessories, Fixation, Spinal Interlamina	LYP	21 CFR 888.3050
Appliance, fixation, spinal interlaminal	KWP	
Orthosis, spine, plate, laminoplasty, metal	NQW	
Spinous process plate	PEK	
Anterior staple as supplemental fixation for fusion	PHQ	21 CFR 888.3060
Appliance, Fixation, Spinal Intervertebral Body	KWQ	
Implant, fixation device, spinal	JDN	
Spinal vertebral body replacement device	MQP	
Orthosis, spinal pedicle fixation	MNI	21 CFR 888.3070
Orthosis, spinal pedicle fixation, for degenerative disc disease	NKB	
Orthosis, spondylolisthesis spinal fixation	MNH	
Pedicle screw spinal system, adolescent idiopathic scoliosis	OSH	
Posterior metal/polymer spinal system, fusion	NQP	
Intervertebral fusion device with bone graft, cervical	ODP	21 CFR 888.3080
Intervertebral fusion device with bone graft, lumbar	MAX	

Devices included in the labeling compliance date extension, if such devices are also single use implants intended to be sterilized before use		
Device	**Product Code**	**Classification Regulation**
Intervertebral fusion device with bone graft, thoracic	PHM	21 CFR 888.3080
Intervertebral fusion device with integrated fixation, cervical	OVE	
Intervertebral fusion device with integrated fixation, lumbar	OVD	
Wire, surgical	LRN	Preamendments Unclassified
System, facet screw spinal device	MRW	
Growing rod system	PGM	
Growing rod system, magnetic actuation	PGN	

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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