*Contains Nonbinding Recommendations*

# Global Unique Device Identification Database (GUDID): Data Submission Compliance Date of September 24, 2015

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# Guidance for Industry and Food and Drug Administration Staff

**Document issued on August 14, 2015.**

For questions for the Center for Devices and Radiological Health regarding this document, contact UDI Regulatory Policy Support, 301-796-5995, email: GUDIDSupport@fda.hhs.gov.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 240-402-7800.



**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**
**Center for Biologics Evaluation and Research**

## Preface

# Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Additional copies are available from the Center for Biologics Evaluation and Research (CBER) by written request, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20903, or by calling 1-800-835-4709 or 240-402-7800, by email, ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

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***This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA offices responsible for this guidance as listed on the title page.***

On September 24, 2013, FDA issued regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices (78 FR 58786) (the UDI Rule). FDA established a set of compliance dates, by device classification, for compliance with required labeling and data submission to the Global Unique Device Identification Database (GUDID) under the UDI Rule. For class III devices and devices licensed under the Public Health Service Act, the compliance date was September 24, 2014. FDA granted requests for extensions to the compliance date some of which expire on September 24, 2015. For implantable, life sustaining and life supporting devices (other than class III devices which had a compliance date of September 24, 2014), the compliance date is September 24, 2015.

On August 7, 2015, due to a security vulnerability in GUDID, FDA decided to take the system offline until a patch is implemented. Due to the temporary unavailability of the GUDID system, we intend to exercise enforcement discretion to extend the September 24, 2015, GUDID submission compliance date for the implantable, life-supporting and life-sustaining medical devices to October 24, 2015. For extensions granted to class III labelers that expire between August 7 and September 24, 2015, we also intend to exercise enforcement discretion to extend the expiration date of these extensions to October 24, 2015.

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