FDA Unique Device Identification System Final Rule
Fact Sheet
October 2013

Background

On September 24, 2013, the Food and Drug Administration (FDA) issued its Unique Device Identification (UDI) System Final Rule, which establishes a system for adequately identifying medical devices through distribution and use, with a goal of substantially reduce existing obstacles to the adequate identification of medical devices used in the United States.

The rule fulfills a statutory requirement of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that directs the FDA to issue regulations establishing a UDI system for medical devices. It also meets the Food and Drug Administration Safety and Innovation Act (FDASIA) component that included a deadline for publication of this final rule and requirements. Implementation deadlines are staggered over a period of seven years and are summarized in the table below.

Purpose

The purpose of this regulatory action is to make it possible to rapidly and definitively identify a medical device and key attributes that affect its safe and effective use through the use of UDI. This process is designed to reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use.

As a result of this final rule, most medical devices distributed in the United States will be required to carry a unique device identifier (UDI). The UDI will be an unique numeric or alphanumeric code consisting of two parts.

- A device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and
- A production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device.

The goal of the FDA is, upon full implementation of the UDI system, it will:

- **Reduce medical errors** by enabling health care professionals and others to more rapidly and precisely identify a device and obtain important information concerning the characteristics of the device.
- **Enhance analysis of devices** on the market by providing a standard and clear way to document device use in electronic health records, clinical information systems, claim data sources and registries.
- **Provide a standardized identifier** that will allow manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.
- **Address counterfeiting/diversion and prepare for medical emergencies** by providing a foundation for a global, secure distribution chain..
- **Facilitate a global identification system** - lead to the development of a medical device identification system that is recognized around the world.

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Summary of Compliance Dates for the UDI Final Rule

The FDA established a set of compliance dates that will phase-in the requirements of this rule in stages, over a period of 7 years. The table below outlines key compliance dates in the UDI final rule.

Compliance Date	Requirement
1 year after publication of the final rule (September 24, 2014)	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b).
2 years after publication of the final rule (September 24, 2015)	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18.
	A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must a bear UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45. Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b).
	Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
3 years after publication of the final rule (September 24, 2016)	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
	The labels and packages of class II medical devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Class II stand-alone software must provide its UDI as required by § 801.50(b).
	Data for class II devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
5 years after publication of the final rule (September 24, 2018)	A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
	The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20. Dates on the labels of <u>all</u> devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by § 801.18.
	Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. Class I stand-alone software must provide its UDI as required by § 801.50(b).
7 years after publication of the final rule (September 24, 2020)	Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must a bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
Compliance dates for all other provisions of the final rule. Except for the provisions listed above, FDA requires full compliance with the final rule as of the effective date that applies to the provision.	