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CLIENT ALERT

FDA Issues New Guidance on the Unique Device Identification System

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On August 13, 2014, the United States Food and Drug Administration (FDA) issued new guidance for industry on the implementation of a September 24, 2013 rule establishing the Unique Device Identifier (UDI) System. The UDI System requires medical device manufacturers to include a UDI on most device labels. The System is intended to help health care professionals and consumers rapidly and accurately identify the medical devices they use, thus allowing them to more accurately report adverse events. With better data, FDA hopes it can identify and correct problems more quickly.

The newly issued UDI Guidance provides an overview of the new regulatory requirements and discusses the actions a small entity should take to comply. Specifically, it outlines label and data submission requirements for all medical devices in commercial distribution in the United States. Some of the most noteworthy requirements detailed in the UDI Guidance include the following:

- With some exceptions, noted below, FDA will require a UDI on every device label and package.
  - If the device is considered a class I medical device, however, labelers may use a Universal Product Code (UPC) to serve as the UDI on the device label and package. A UPC is the product identifier used to identify an item sold at retail in the United States.
  - Class I devices that FDA has by regulation exempted from the good manufacturing practice (GMP) requirements are exempted entirely from UDI requirements.
  - In addition, a finished device manufactured and labeled prior to its applicable compliance date and held in inventory is also exempted

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from the UDI requirements for three years after the compliance date. A finished device is any device or accessory to any device that is suitable for use or capable of functioning.

- In order for a medical device labeler to assign a UDI to a device, the labeler must participate in a system administered by an accredited issuing agency. FDA keeps a list of accredited issuing agencies.

- Each UDI must be in both easily readable plain-text and in a form that uses automatic identification and data capture (AIDC) technology – usually a bar code.

- Each device identifier (DI), or mandatory, fixed portion of the UDI, is used to identify only one version or mode.

  - Labelers must assign a new DI to their medical device if they change the device so that it becomes a new version or model.

  - Additionally, if labelers create a new device package, they must assign a new DI to that new package. A device package is a package that contains a fixed quantity of a particular version or model of a device.

    - Thus, according to the FAQs issued on the guidance, if a device is sold in individual device packages boxes of thirty (30) devices, and in cartons that contain twelve (12) boxes of thirty (30) device packages, a different DI would be required to appear on the individual device package.

  - If a labeler discontinues a version or model of a device, it may not reassign the DI to another device.

- If a UDI is required, labelers must submit specific information to the Global Unique Device Identification Database (GUDID) electronically. The GUDID is an FDA-administered database that serves as the repository of key device identification information to facilitate the identification of medical devices through their distribution and use.

- **In order to gain access to the GUDID, each labeler must first request an account. Visit "Request a GUDID Account" to learn more about this process.**

- **The information required for submission is relatively basic and includes the following: the point of contact for the labeler; the DI of the UDI; the proprietary, trade, or brand name of the device as it appears on the label of the device; and any version or model number or similar reference that appears on the label of the device.**

UDI requirements apply to devices placed into commercial distribution *after* the compliance date that applies to the device. Devices must be in compliance with UDI requirements by the following dates:

Type of Device	Compliance Date
Class III devices	September 24, 2014
Class I, Class II, and unclassified devices that are implantable, life-supporting, or life-sustaining	September 24, 2015
Class II devices	September 24, 2016
Class I, unclassified, or not classified devices	September 24, 2018

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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