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Unique Device Identifier System: Frequently Asked Questions, Vol. 1

Guidance for Industry and Food and Drug Administration Staff

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

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800, email: ocod@fda.hhs.gov.

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

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Guidance for Industry and Food and Drug Administration Staff

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I. Introduction

Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and section 614 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) amended the Federal Food, Drug, and Cosmetic Act to add section 519(f), which directs FDA to publish regulations establishing a unique device identification system for medical devices. On September 24, 2013, FDA published a final rule establishing a unique device identification system (the UDI Rule). While some parts of the rule became effective on October 24, 2013 and some became effective on December 23, 2013, most requirements within the rule have later compliance dates, as will be explained in Section A.2. of this document. In developing the UDI Rule, FDA solicited input from a variety of stakeholders (e.g., manufacturers, global regulatory bodies, the clinical community, patient advocates) to ensure that as many perspectives were incorporated as possible.

This guidance document provides clarification of key provisions of the UDI Rule.

Throughout this guidance document, the terms "we," "us" and "our" refer to FDA staff from the Center for Devices and Radiological Health (CDRH or the Center) and the Center for Biologics Evaluation and Research (CBER). "You" and "your" refers to the labeler.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and

should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

A. UDI Basics

A.1. Question: What products are subject to the requirements of the UDI Rule?

All devices, as defined by 21 USC 321(h), are subject to the requirements of the UDI Rule, unless an exception or alternative has been granted.

A.2. Question: By what date must a device be in compliance with UDI requirements?

Summary of Compliance Dates for UDI Implementation

	Finished devices manufactured and labeled as of the compliance date established by FDA	
Device	**Label/GUDID/Date Format Requirements**	**Direct Mark Requirements[2]**
Class III (including class III I/LS/LS)[1] Devices licensed under the PHS Act Humanitarian Use Devices	September 24, 2014	LS/LS Class III devices and HDEs must be directly marked by September 24, 2015 All other class III devices must be directly marked by September 24, 2016
I/LS/LS (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II	September 24, 2016	September 24, 2018
Class I, unclassified, or not classified	September 24, 2018	September 24, 2020

[1]I/LS/LS = implantable, life-supporting, or life-sustaining
[2]Direct mark requirements are in addition to label/GUDID/date format requirements.

For details on UDI compliance dates, see the UDI final rule (Sept. 24, 2013).

A.3. Question: What are the parts of a UDI?

As defined in 21 CFR 801.3, a UDI on a device label or package is composed of two parts:

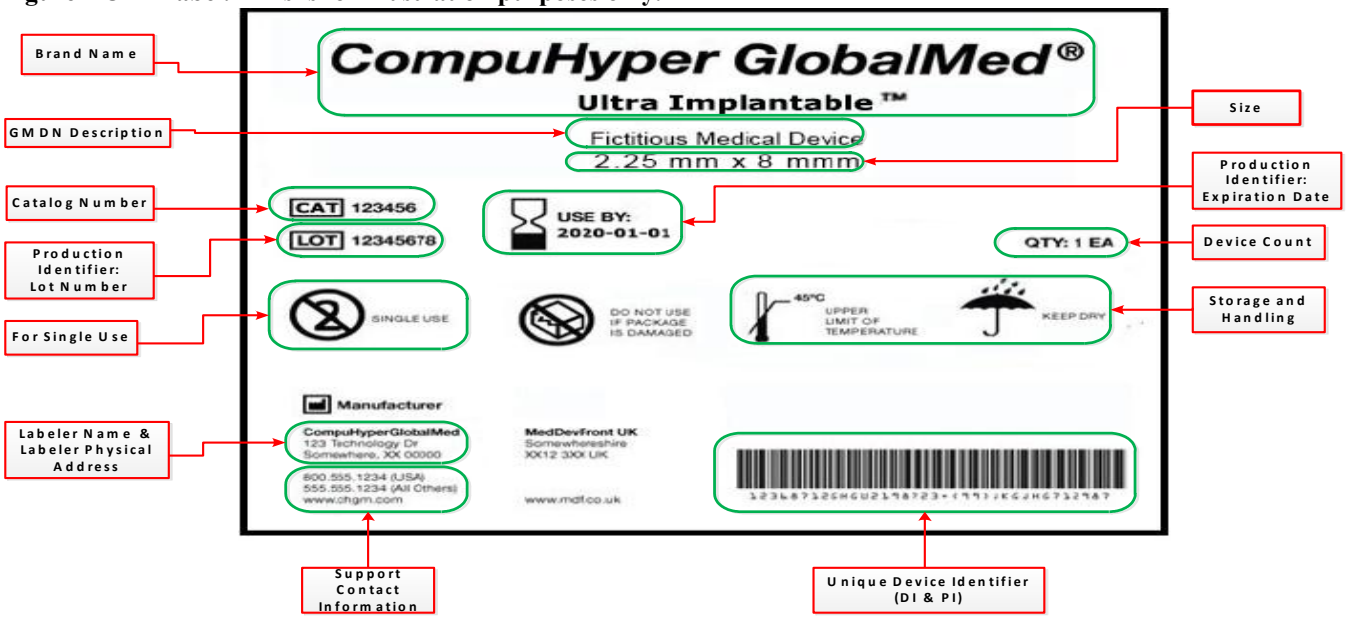
1. Device Identifier (DI)—a mandatory, fixed portion of a UDI that identifies (1) the labeler and (2) the specific version or model of a device;

and

2. Production Identifier(s) (PI)—a conditional, variable portion of a UDI. If any of the following is included in the label of a device, it must also be included in the PI. Any identifiers other than the five listed below are outside the scope of FDA regulated UDI. Each of these five identifiers may also be called a "PI."

- the lot or batch number within which a device was manufactured;
- the serial number of a specific device;
- the expiration date of a specific device;
- the date a specific device was manufactured;
- for an HCT/P regulated as a device, the distinct identification code required by 21 CFR §1271.290(c).

Figure 1 UDI Label. This is for illustration purposes only.



A.4. Question: Is there a standard format for dates on the device label?

Whenever the label of a medical device includes a printed expiration date, date of manufacture, or any other date intended to be brought to the attention of the user of the device, the date must be presented in the following format: the year, using four digits; followed by the month, using two digits; followed by the day, using two digits; each separated by hyphens. For example, January 2, 2014, must be presented as 2014-01-02. See 21 CFR 801.18(b) for exceptions to this requirement. This requirement only applies to plain text dates on the device label. Dates in the AIDC technology portion of the UDI, or in the device history record, for example, are not subject to these date format requirements. In the event that a medical device expires in a particular month, but not a particular date, the labeler may choose the last day of the month for the date field because the date field is a requirement of the new format.

The standard date format is required for all medical devices unless excepted. This change should be implemented on the device label by the UDI compliance date for that device. Devices excepted from or not subject to the UDI regulation, must implement the standard date format by September 2018.

A.5. Question: What is a device package?

For purposes of UDI label and GUDID submission requirements, a device package is a package that contains a fixed quantity of a particular version or model of a device. In order to adequately identify a device throughout distribution and use, the various package configurations, i.e. each different type of package, must have a unique identifier, 21 CFR 801.20(a)(2). Thus, 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, on the box of thirty packages, and on the carton of twelve boxes of thirty device packages. See Section 3.1.2.1 of the Guidance titled "Global Unique Device Identification Database (GUDID)" issued on June 27, 2014, for more information.

A.6. Question: Are single-use devices required to bear a UDI?

Generally, a single-use device is required to bear a UDI on its label. One general exception to that requirement is where individual single-use devices all of a single version or model are distributed together in a single device package and intended to be stored in that device package until removed for use. Then the UDI is not required on the device label, but is still required on the device package. This exception is not available for any implantable device. Also, if the devices are intended for individual commercial distribution, the device label and package for these individual devices is required to bear a UDI. 21 CFR 801.30(a)(3) Single use devices are not required to bear a permanent UDI, even if re-processed. 21 CFR 801.45(d)(3).

A.7. Question: In what form should a UDI appear on a device label and on device packages?

21 CFR § 801.40(a) requires each UDI to be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. AIDC means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process. Plain text consists of legible characters that can easily be read by people. No particular font or point size is specified for the UDI; rather, the UDI would be subject to existing requirements that govern medical device labels, including 21 CFR § 801.15, concerning prominence of required label statements.

A.8. Question: What Automatic Identification Data Capture (AIDC) technologies are specified for UDI?

We do not specify what AIDC technologies may be used, because the most appropriate technology will vary considerably depending on the type of device and its intended uses, and because the available technologies are likely to evolve and advance over time. The AIDC technology may be a bar code or any other technology that serves the same objectives. We

recommend you contact your FDA accredited issuing agency for information on the AIDC system it uses.

The AIDC version facilitates rapid and accurate identification of the device, particularly by the device user, and should be obvious to the user. While the presence of a bar code on the UDI label is visible and therefore immediately obvious, the presence of other AIDC technologies, such as RFID and near-field communication, may not be so obvious to the device user. Therefore, if the AIDC technology is not visible on the label of the device or on the device package, the device label or on the device package must provide notice of the presence of AIDC technology. No particular method for providing this notice is specified.

A.9. Question: Does software need to be labeled with a UDI?

The UDI Rule does not provide any special requirements for a device that contains software as a component of the device, but does require stand-alone medical software to be labeled with a UDI.

All stand-alone software, whether packaged or unpackaged (e .g., software downloaded from a website), must provide its UDI through either or both of the following: (1) An easily readable plain-text statement displayed whenever the software is started; (2) An easily readable plain-text statement displayed through a menu command (e.g., an "About..." menu command).

Stand-alone software that is distributed in packaged form is subject to the same UDI labeling requirements as any other medical device -- the device label and device package must bear a UDI in plain-text and AIDC formats according to 21 CFR 801.40(a). Stand-alone software that is distributed in both packaged and not packaged form may be identified with the same DI. Stand-alone software that is not distributed in packaged form must convey the version number in its production identifier.

A.10. Question: What changes would require a new device identifier?

21 CFR § 830.50(a) states that "whenever you make a change to a device that is required to bear a unique device identifier (UDI) on its label, and the change results in a new version or model, you must assign a new [DI] to the new version or model." "Version or model" is defined under 21 CFR § 801.3 as "all devices that have the specifications, performance, size and composition, within limits set by the labeler. The labeler has the responsibility to determine whether device upgrades or variations constitute different models or versions. Under 21 CFR § 830.50(a), a software update will require a new DI only if the upgrade results in a new version or model. In addition, there are attributes within the GUDID device record that cannot be changed. When these particular attributes change value, FDA has determined that these changed attributes represent a new device requiring a new DI, and the new device record will be required to represent the new version/model.

A.11. Question: Are devices manufactured and labeled prior to the compliance date subject to UDI requirements?

UDI requirements apply to devices placed into commercial distribution after the compliance date that applies to the device. A finished device manufactured and labeled prior to its compliance date and held in inventory is excepted from UDI requirements for three years after the compliance date. This exception applies to both products held in inventory by the labeler and those consigned to a hospital or other potential purchaser and held in inventory, but not yet purchased, by the potential purchaser. This exception applies to all UDI requirements.

A.12. Question: What are the UDI conforming amendments?

The UDI final rule makes changes to certain parts of 21 CFR governing FDA's existing regulatory systems and processes to integrate UDIs and device identifiers. These changes, known as the conforming amendments, affect part 803 (Medical Device Reporting), part 806 (Medical Devices; Reports of Corrections and Removals), part 814 (Premarket Approval of Medical Devices), part 820 (Quality System Regulation), part 821 (Medical Device Tracking Requirements), and part 822 (Postmarket Surveillance).

A.13. Question: When do the conforming amendments in the Unique Device Identification System Final Rule become effective?

The conforming amendments in the Unique Device Identification System Final Rule went into effect on December 23, 2013. While these provisions have been in effect since December 23, 2013, they may not have practical effect until other provisions must be complied with. For example, the amendments to parts 820 and 822 will have no practical effect until 1 year after publication of the final rule, when class III devices become subject to UDI labeling requirements, and at that time only will apply to Class III devices and devices licensed under the Public Health Service Act.

A.14. Question: How do labelers obtain UDIs?

For purposes of maintaining standardization, FDA requires all UDIs to be issued under a UDI system operated by an FDA-accredited issuing agency.

A.15. Question: What is an issuing agency?

An issuing agency is an organization accredited by FDA to operate a system for the issuance of UDIs according to the criteria and processes outlined in 21 CFR 803 Subpart C—FDA Accreditation of an Issuing Agency. Each FDA-accredited issuing agency will be permitted to design and operate its device identification system in any manner that conforms with the technical standards incorporated by reference in part 830. In order for a 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.

B. UDI Placement

B.1. Question: Who is responsible for complying with UDI requirements including placing the UDI on device label and packages?

The labeler is the person who causes a label to be applied to a device, or who causes the label to be replaced or modified, with the intent that the device will be introduced into interstate commerce without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler.

B.2. Question: Where is the UDI to be placed?

The UDI is to be placed on the device label, device packages, and, if the device is intended to be used more than once and reprocessed between uses, on the device itself.

B.3. Question: If there is no room for the UDI on the current label, can the labeler design a new label with just the UDI and place it on the package?

The final rule does not specify the type of label that is required to bear a UDI. It is up to the labeler to determine an appropriate method to apply the UDI to the device label. An add-on label, in some instances, may be appropriate. However, a UDI must be included on the device label and every device package.

C. Global Unique Device Identifier Database (GUDID)

C.1. Question: What is the GUDID?

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.

C.2. Question: What information is required to be reported to the GUDID, and who should submit it?

21 CFR §830.310 describes the information that must be reported to FDA by the labeler. Further clarification can be found in the guidance titled "Global Unique Device Identification Database (GUDID)" issued on June 27, 2014, and the GUDID Data Elements Table available from the UDI website.

C.3. Question: How does a labeler get access to GUDID in order to submit UDI information for devices?

Each labeler must first request a GUDID account. Please visit Request a GUDID Account to learn more this process.

C.4. Question: What is a FDA listing number and is it a required element in the GUDID?

When a device is listed, FDA assigns a listing number to that device. The FDA Listing Number is a required data element in the GUDID. To determine the listing number of a device, log into your FURLS (FDA's Unified Registration and Listing System) account if you have one, to look up your devices' listing numbers and download all of your listing information. Additionally, you can contact the Registration and Listing Office by phone at 301-796-7400 or by email at reglist@cdrh.fda.gov. However, the Registration and Listing Office will only give out the listing number to the person(s) noted as the official correspondent (OC) or owner/operator contact (OO) for the company that lists the product. If you are not the OO or OC and you don't know who in your company is, you can look up that information at Establishment Registration and Device Listing Database.

D. Direct Marking

D.1. Question: When does a device need to be directly marked with a UDI?

Devices intended to be used more than once and intended to be reprocessed before each use are required to bear a permanent UDI affixed to the device itself unless one of the 21 CFR §801.45(d) exceptions applies.

D.2. Question: What are the 21 CFR §801.45(d) exceptions from direct marking requirements?

Direct marking exceptions apply to any device that meets any of the following four criteria:

(a) Any type of direct marking would interfere with the safety or effectiveness of the device;
(b) the device cannot be directly marked because it is not technologically feasible;
(c) the device is a single-use device and is subjected to additional processing and manufacturing for the purpose of an additional single use; or
(d) the device has been previously marked under 21 CFR 801.45(a).

D.3. Question: Do implantable devices need to be directly marked with a UDI?

The UDI Rule does not require an implantable device to be directly marked with its UDI. CDRH believes that the UDI label and package requirements will provide for adequate identification of an implantable device up to the point where it is implanted. CDRH also acknowledges the common practice of recording information about implanted devices both in the patient's health record, and on a card provided to the patient, and we expect health care providers will incorporate UDIs into both of these types of records.

D.4. Question: What is the UDI format used for directly marked devices?

When the device must directly marked with a UDI, either or both of the following must be provided: easily readable plain-text and/or AIDC technology or any alternative technology that will provide the UDI of the device on demand. The device label, however, must have a UDI presented in both easily readable plain-text and AIDC technology.

D.5. Question: For devices requiring direct marking, may the UDI be affixed via a sticker rather than etching or laser marking the UDI on the instrument itself?

We do not believe it is appropriate to specify any particular approach because it would be difficult to define ''normal'' usage or ''normal'' cleaning procedures for all devices, and technological advancements may change what constitutes normal usage and appropriate cleaning procedures. However we expect the direct mark to be as permanent as the normal life expectancy of the device, and it needs to be capable of withstanding the normal usage and cleaning procedures specified for the device.

E. Exceptions, Alternatives and Exemptions

E.1. Question: Are class I devices subject to UDI requirements?

Class I devices are subject to UDI requirements, with certain exceptions:

1. Class I devices are not required to include a production identifier (PI).
2. Class I devices that bear a Universal Product Code (UPC) on their labels and device packages are deemed to meet all UDI labeling requirements of 21 CFR 801 subpart B. 21 CFR 801.40(d). Labelers of such devices would still be required to comply with requirements to submit data to the GUDID.
3. Class I devices that FDA has by regulation exempted from the good manufacturing practice requirements of 21 CFR 820 (other than record keeping requirements and complaint files) are excepted entirely from UDI requirements.

E.2. Question: Are 510(k) exempt products subject to UDI requirements?

Yes, unless an exception applies. There is no general exception for 510(k) exempt products.

E.3. Question: Are Humanitarian Use Devices (HUDs) subject to UDI requirements?

Yes, unless an exception applies. They are Class III medical devices and have the same compliance dates as other Class III devices.

E.4. Question: Does the UDI final rule provide for any general exceptions from UDI requirements?

Yes. 21 CFR 801.30 outlines a number of general exceptions for certain device categories.

E.5. Question: May a labeler request an exception from UDI labeling requirements for situations not covered by the general exceptions identified in 21 CFR 801.30?

Yes. Requests involving an exception or alternative to UDI requirements that do not fit into the categorical exceptions of the final rule may be submitted by the labeler and evaluated by FDA according to the process and criteria described in 21 CFR 801.55 --- Request for an exception from or alternative to a unique device identifier requirement.