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Unique Device Identification System: Small Entity Compliance Guide

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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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Unique Device Identification System Small Entity Compliance Guide

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products, medical devices, the nation's food supply, cosmetics, dietary supplements, and products that give off radiation; and for regulating tobacco products.

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). Some parts of the rule became effective on October 24, 2013; the remaining parts became effective on December 13, 2013. Certain requirements within the rule have later compliance dates, as will be explained in Section VI 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 is intended primarily to provide information to the medical device industry, including small businesses, concerning FDA's September 24, 2013, final rule establishing a unique device identification system; see 78 FR 58786 et seq. It provides an overview of the UDI Rule's regulatory requirements and discusses the actions a small entity should take to meet those requirements. Other guidance documents, such as the guidance document titled Global Unique

Device Identification Database (GUDID) and issued on June 25, 2014, discuss in greater detail the technical implementation of the UDI Rule.

Throughout this guidance document, the terms "we," "us" and "our" refer to FDA staff from CDRH 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 FDA'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 FDA guidance means that something is suggested or recommended, but not required.

II. Background

Under Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121) we are required to publish one or more guides that assist small entities in complying with each rule or group of related rules for which we are required to prepare a final regulatory flexibility analysis under 5 U.S.C. 605(b).

The UDI Rule establishes a UDI system. It requires the labels and device packages of medical devices distributed in the United States include a unique device identifier (UDI), unless we grant an exception or alternative to UDI label requirements. As will be explained later, this UDI will be in both easily readable plain-text and Automatic Identification and Data Capture (AIDC) technology—usually a bar code. The UDI Rule also requires specified product information be submitted to FDA's Global Unique Device Identification Database (GUDID). Most of this information in GUDID will be made available to the public. When fully implemented, the UDI system will serve several important public health objectives:

- It will facilitate the healthcare community, industry, and the public's rapid and accurate identification of a device using the UDI that appears on the device's label and device package.
- Medical providers, patients and others will be able to more easily access important information concerning the device, thereby reducing medical errors.
- It will allow more accurate reporting, reviewing, and analyzing of adverse event reports so that problems can be identified and corrected more quickly.
- It will provide a standard and clear way to document device use in electronic health records, clinical information systems, claims data sources and registries, leading to a more robust postmarket surveillance system which can be leveraged to support premarket approval or clearance of new devices and new uses of currently marketed devices.
- It will enable manufacturers, distributors and healthcare facilities to more effectively manage medical device recalls.

- It will provide a foundation for a global, secure distribution chain that will help address counterfeiting and diversion, and prepare for medical emergencies.

III. Overview

The UDI Rule establishes label and data submission requirements for all medical devices in commercial distribution in the United States. There are two main parts to the UDI system; there is a label requirement and a data submission requirement. Every medical device label and every device package must include a UDI, unless we have granted an exception or alternative. The rule lists general exceptions and outlines the procedure for requesting a specific exception or alternative. The UDI Rule specifies the requirements for how the UDI will appear on the device label and package. The UDI Rule also specifies data submission and record keeping requirements. It requires all UDIs to be issued under a system operated by an FDA-accredited issuing agency. It also outlines the procedure to apply for FDA-accreditation as an issuing agency, specifies the information that the applicant must provide to FDA, and lists the criteria we will apply in evaluating applications. The UDI Rule provides for the suspension and revocation of the accreditation of an issuing agency, and explains the circumstances under which we may act as an issuing agency. The UDI system will be phased in over a seven year period, through an established set of compliance dates, to ensure a smooth implementation, and to spread the costs and burdens over time. Greater details of the UDI Rule are set out in the following sections of this document.

IV. Definitions

The following terms are defined in the UDI Rule:

Automatic identification and data capture (AIDC)

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. 21 CFR 801.3.

Center Director

The Director of the Center for Devices and Radiological Health or the Director of the Center for Biologics Evaluation and Research, depending on which Center has been assigned lead responsibility for the device. 21 CFR 801.3.

Combination product

Includes:
(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect. 21 CFR 801.3 citing 21 CFR 3.2(e).

Convenience kit

Two or more different medical devices packaged together for the convenience of the user. 21 CFR 801.3.

Device Identifier (DI)

A mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. 21 CFR 801.3.

Unique Device Identifier (UDI) = Device Identifier (DI) + Production Identifier (PI)

Device package

A package that contains a fixed quantity of a particular version or model of a device. 21 CFR 801.3.

Expiration date

The date by which the label of a device states the device must or should be used. 21 CFR 801.3.

FDA, we, or us

The Food and Drug Administration. 21 CFR 801.3.

Finished device

Any device or accessory to any device that is suitable for use or capable of functioning. 21 CFR 801.3.

Federal Food, Drug, and Cosmetic Act

21 U.S.C. 321 *et seq.*, as amended.

Global Unique Device Identification Database (GUDID)

The database that serves as a repository of information to facilitate the identification of medical devices through their distribution and use. 21 CFR 801.3.

Human cells, tissues, or cellular or tissue-based product (HCT/P) regulated as a device

An HCT/P,[1] as defined in 21 CFR 1271.3(d), that does not meet the criteria set forth in § 1271.10(a) and that is also regulated as a device. 21 CFR 801.3.

[1] § 1271.3(d) - Human cells, tissues, or cellular or tissue-based products (HCT/Ps) means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The following articles are not considered HCT/Ps:
(1) Vascularized human organs for transplantation;
(2) Whole blood or blood components or blood derivative products subject to listing under 21 CFR Parts 607 and 207 of this chapter, respectively;
(3) Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered an HCT/P;
(4) Minimally manipulated bone marrow for homologous use and not combined with another article (except for water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow);
(5) Ancillary products used in the manufacture of HCT/P;
(6) Cells, tissues, and organs derived from animals other than humans; and
(7) In vitro diagnostic products as defined in § 809.3(a) of this chapter.
(8) Blood vessels recovered with an organ, as defined in 42 CFR 121.2, that are intended for use in organ transplantation and labeled "For use in organ transplantation only."

The criteria listed in § 1271.10(a):
(1) The HCT/P is minimally manipulated;
(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
(3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
(4) Either:
(i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
(ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
(a) Is for autologous use;
(b) Is for allogeneic use in a first-degree or second-degree blood relative; or
(c) Is for reproductive use.

Implantable device

A device that is intended to be placed in a surgically or naturally formed cavity of the human body. A device is regarded as an implantable device for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner of Food and Drugs determines otherwise in order to protect human health. 21 CFR 801.3.

Issuing agency

An organization accredited by FDA to operate a system for the issuance of unique device identifiers. 21 CFR 830.3.

Label

A display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper. 21 CFR 801.3 citing 21 U.S.C. 321(k).

Labeler

(1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and
(2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler. 21 CFR 801.3.

Lot or batch

One or more finished devices that consist of a single type, model, class, size, composition, or software version manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. 21 CFR 801.3.

Production Identifier (PI)

A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
(a) The lot or batch within which a device was manufactured;
(b) The serial number of a specific device;

(c) The expiration date of a specific device;
(d) The date a specific device was manufactured;
(e) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c) of this chapter. 21 CFR 801.3.

Unique Device Identifier (UDI) = Device Identifier (DI) + Production Identifier (PI)

Shipping container

A container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another. 21 CFR 801.3.

Small business

A medical device manufacturer with 500 or fewer employees, or a medical device relabeler or repackager with 100 or fewer employees. 21 CFR 830.3.

Specification

Any requirement with which a device must conform. 21 CFR 801.3.

Unique Device Identifier (UDI)

An identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 830.20 of this chapter. A unique device identifier is composed of a (1) device identifier and (2) production identifier.[2] 21 CFR 801.3.

Universal Product Code (UPC)

The product identifier used to identify an item sold at retail in the United States. 21 CFR 801.3.

Version or model

All devices that have specifications, performance, size, and composition, within limits set by the labeler. 21 CFR 801.3.

[2] § 830.20 - A unique device identifier (UDI) must:
(a) Be issued under a system operated by FDA or an FDA-accredited issuing agency;
(b) Conform to each of the following international standards:
(1) ISO/IEC 15459-2, which is incorporated by reference at § 830.10;
(2) ISO/IEC 15459-4, which is incorporated by reference at § 830.10; and [*58826]
(3) ISO/IEC 15459-6, which is incorporated by reference at § 830.10.
(c) Use only characters and numbers from the invariant character set of ISO/IEC 646, which is incorporated by reference at § 830.10.

V. UDI Final Rule

A. Requirement to bear a UDI label

The UDI Rule requires a UDI on every device label and package. There are general exceptions to this requirement which are explained in Section V.E.1.[3] Each UDI must be in both easily readable plain-text and in a form that uses automatic identification and data capture (AIDC) technology. We explain this more in Section V.B.1.

The "labeler" has the responsibility for complying with the UDI label, data submission, and records requirements. Therefore, it is important to determine whether you fit the definition of "labeler". The definition of "labeler" is included in Section IV. In most instances, the device manufacturer is the labeler. But this is not always the case. For example, if you remanufacture and place a new label on a device, you are a labeler for purposes of the UDI Rule.

1. Device Identifier and Production Identifier

(UDI = DI + PI)

A UDI typically comprises both a device identifier (DI) and a production identifier (PI). These terms are defined in Section IV. However the UDI of a class I device is not required to include a PI.

a. Device Identifier

The device identifier (DI) is a mandatory, fixed portion of the UDI that identifies (1) you as the labeler, and (2) the specific model or version of your device. The DI is used to look up information about the device in the database administered by FDA called the GUDID. The GUDID is discussed further in Section V.D.

Each DI is used to identify only one version or model. You must assign a new DI if you change a device so that it becomes a new version or model. Also, if you create a new device package such as a new package configuration or another packaging level, you must assign a new DI to that new package. Keep in mind, you as the labeler, and not FDA, decides what is a separate version or model of your device for purposes of requiring a DI.

If you discontinue a version or model of a device, you may not reassign the DI to another device. If you reintroduce a discontinued version or model of a device, you may use the DI assigned to that particular version or model of the device at the time that you discontinued it.

[3] If you do not fit within one of the general exceptions, Section V.E.2 explains how to request a specific exception or alternative.

b. Production Identifier (PI)

A production identifier (PI) is a conditional, variable portion of the UDI. If you have included any of following information in your device label, that information must also be included in the PI portion of the UDI:

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

For ease of use, this type of information is referred to as "PI. Please note: any identifiers beyond those five listed above are outside the scope of the FDA-regulated UDI.

2. Voluntary Labeling of Device with UDI (21 CFR 801.35)

If your device is not required to have a UDI, you may still voluntarily comply with UDI requirements, including label and data submission requirements. If you voluntarily comply with the UDI label requirements, you are not required to submit data to the GUDID, but you may volunteer to do so.

3. In Vitro Diagnostic Products (21 CFR 801.119)

In vitro diagnostic products must comply with both UDI label requirements and the label requirements in 21 CFR 809.10.

4. Discontinuation of legacy FDA identification numbers assigned to medical devices (NHRIC and NDC numbers) (21 CFR 801.57)

If your device has a National Health-Related Item Code (NHRIC) or National Drug Code (NDC) assigned to it, and a UDI is also required, the NHRIC or NDC will be rescinded on the device's UDI compliance date (see Section VI for compliance dates). As of the UDI compliance date, you may no longer put a NHRIC or NDC number on your device label or package.

If your device is not required to bear a UDI, any NHRIC or NDC assigned to it will be rescinded on September 24, 2018, and you will not be permitted to put the NHRIC or NDC on the device label or package.

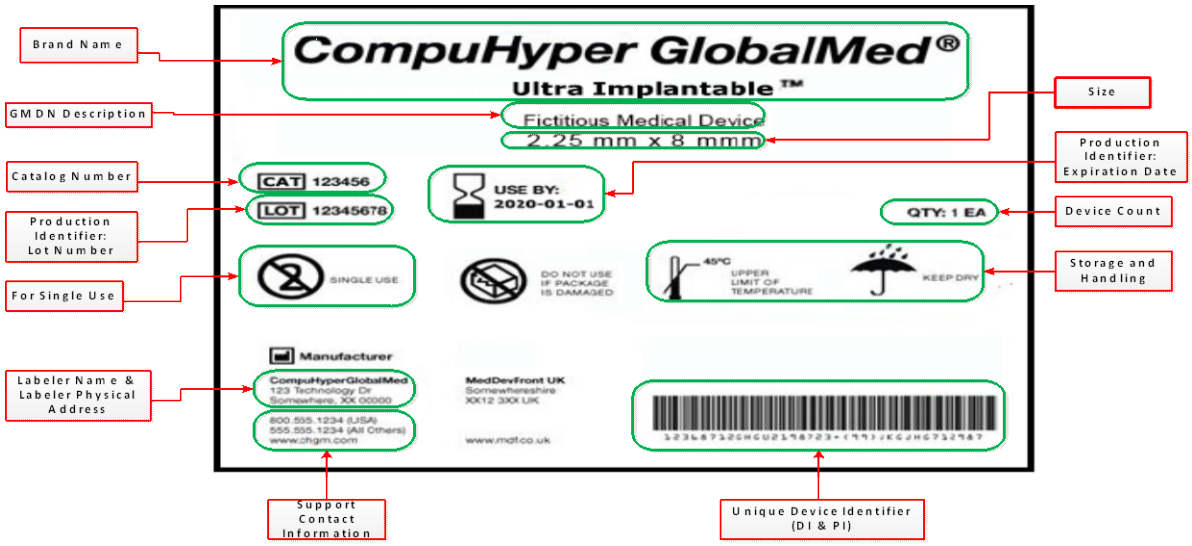

Figure 1 UDI Label. This is for illustration purposes only

B. UDI Label Requirements

1. Form of a UDI (21 CFR 801.40)

Every UDI must be presented in two forms:

(1) Easily readable plain-text, and
(2) Automatic identification and data capture (AIDC) technology. If the AIDC technology is not evident upon visual examination of the label or package, the label or package must disclose the presence of the AIDC technology.

If your device is class I, you may use a Universal Product Code (UPC) to serve as the UDI on the device label and package. In addition, the UDI on your class I devices are not required to include a PI.

2. Technical Requirements for a UDI (21 CFR 830.20)

There are very specific technical requirements for UDIs. FDA-accredited issuing agencies (IAs) are required to issue UDIs that conform to the following ISO standards (FDA-accredited issuing agency is explained in detail in Section V.C.):

(a) ISO/IEC 15459-2:2006(E), Information technology—Unique identifiers—Part 2: Registration procedures (second edition; March 1, 2006);
(b) ISO/IEC 15459-4:2008(E), Information technology—Unique identifiers—Part 4: Individual items (second edition; July 15, 2008); and
(c) ISO/IEC 15459-6:2007(E), Information technology—Unique identifiers—Part 6: Unique identifier for product groupings (first edition; June 15, 2007).

The UDI may use only characters and numbers from the invariant character set of ISO/IEC 646:1991(E), Information technology—ISO 7-bit coded character set for information interchange (third edition; December 15, 1991).

3. Format for Dates Provided on a Label (21 CFR 801.18)

If your device label includes a printed expiration date, date of manufacture, or any other date that you intend to be brought to the attention of the user, the dates must be presented in a specified format that is consistent with international standards and international practice. This format is: 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.

There are some limited exceptions pertaining to combination products and radiation emitting products that are listed in 21 CFR 801.18(b).

4. Permanent UDI (21 CFR 801.45)

If your device is intended to be used more than once and intended to be reprocessed before each use, your device must have the UDI permanently marked on the device itself. This permanent UDI may be identical to the UDI that appears on the device label, or it may be a different UDI to distinguish the device itself from its packaging. The permanent UDI must be in either or both (1) easily readable plain-text and (2) AIDC form or alternative technology that will provide the UDI of the device on demand.

The permanent UDI requirement does not apply if your device that is intended to be used more than once and intended to be reprocessed before each use meets any of the following criteria:

(1) Any type of direct marking would interfere with the safety and effectiveness of the device;
(2) It is not technologically feasible to directly mark the device;
(3) The device is cleared/approved as a single use device; or
(4) The device already has a permanent UDI directly marked on the device.

If you decide to make use of one of these exceptions, the basis of your decision must be documented in the design history file required by 21 CFR 820.30(j).

5. Stand Alone Software (21 CFR 801.50)

There are no UDI special requirements for a device that contains software as a component of the device, but stand-alone software must be labeled with a UDI. If your stand-alone software is distributed in packaged form, it 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. All stand-alone software, regardless of whether it is or is not distributed in packaged form, that is regulated as a medical device must provide its unique device identifier through either or both of the following:

(1) An easily readable plain-text statement displayed whenever the software is started, and/or
(2) An easily readable plain-text statement displayed through a menu command (e.g., an ''About * * *'' command).

Stand-alone software that is not distributed in packaged form (e.g., when downloaded from a Web site) must also convey the version number in its production identifier.

Stand-alone software that is distributed in both packaged form and in a form that is not packaged may be identified with the same DI.

C. Issuing Agency

You are required to use a UDI system operated by a FDA-accredited issuing agency (IA). An IA may charge a labeler a fee for use of the IA for the issuance of UDIs. Each IA operates a system for assignment of UDIs that meets the requirements listed in Section V.B.2. An IA makes available information concerning its system for assigning UDIs, maintains a list of labelers that use its system for the assignment of UDIs, provides an annual list of labelers to FDA, and upon request provides us with information on a labeler that employs the IA's system for assigning UDIs.

We accredit IAs. The eligibility and accreditation criteria are set out in 21 CFR 830.100. A private organization may apply for accreditation. We may accredit an organization if the system employed by the organization will (1) conform with the ISO standards listed in Section V.B.2.of this document, (2) be available to all users according to a single set of consistent, fair, and reasonable terms and conditions and (3) protect against conflicts of interests between the organization and labelers.

The procedure for FDA initial accreditation and renewal is outlined in 21 CFR 830.110. The initial term of accreditation is three years with renewal terms of seven years. We may suspend or revoke an IA's accreditation if we find that the IA was guilty of fraud in obtaining its accreditation, failed to fulfill the responsibilities required by the UDI Rule, failed to protect against conflicts of interest or has engaged in anticompetitive activity, or has violated the UDI Rule or related regulation.

Under 830.200, under certain conditions, FDA may act as an IA. These conditions include (1) any period where these is no accredited IA, (2) when we determine that a significant number of small businesses would be substantially and adversely affected by the fees required by all accredited IAs, (3) when we determine that it is necessary for the continuation of the UDI system, or (4) when we determine it is appropriate to facilitate or implement an alternative granted under 21 CFR 801.55. When we act as an IA, any labeler may use our IA services,

not only small businesses.

If your IA relinquishes or does not renew its accreditation, you may continue to use the previously assigned DI until the UDI Rule otherwise requires a new DI to be assigned (e.g. a change in version or model).

D. GUDID data submission requirements

In general, if a UDI is required for your device or device package, you are also required to submit the information described below to the GUDID electronically. You may obtain a waiver from electronic submission by submitting a letter requesting a waiver addressed to the CDRH or CBER Center Directorate at the address listed in section V.E.2. If you have already been granted a waiver from electronic submission of 21 U.S.C. 510(p) registration and listing information, you are automatically waived from UDI electronic submission. If granted a waiver from electronic submission, you must submit the required information by letter as described in 21 CFR 830.320(c)(3).

1. Information required (21 CFR 830.310)

a. Concerning the labeler

You must designate one individual to serve as the point of contact with FDA on matters relating to the identification of medical devices marketed by you. This individual may authorize an IA or other person to submit information to us. The contact individual (or other authorized person) shall submit your name and contact information, and the IA(s) you use for issuance of UDIs to the GUDID.

b. Concerning each version or model of a device

For each version or model of a device required to have a UDI on its label, you must submit the following information to the GUDID:

1. The device identifier portion of the UDI assigned to the version or model;
2. When reporting a substitution of a new device identifier, the device identifier that was previously assigned to the version or model;
3. If the device is required to bear a permanent UDI on the device itself, either:
    i. A statement that the device identifier that appears as a permanent marking on the device is identical to that reported under paragraph (b)(1) of this section, or
    ii. The device identifier portion of the UDI that appears as a permanent marking on the device;
4. The proprietary, trade, or brand name of the device as it appears on the label of the device;
5. Any version or model number or similar reference that appears on the label of the device;
6. If the device is labeled as sterile, a statement to that effect;

7. If the device is labeled as containing natural rubber latex that contacts humans, or is labeled as having packaging containing natural rubber latex that contacts humans, a statement to that effect;
8. Whether a patient may be safely exposed to magnetic resonance imaging, nuclear magnetic resonance imaging, or magnetic resonance tomography while using the device, or while the device is implanted in the patient.
9. If the device is available in more than one size, the size of the particular version or model, together with the unit of measure, as it appears on the label of the device;
10. The type of PI that appears on the label of the device;
11. The FDA premarket submission number of a cleared or approved device, or a statement that FDA has by regulation exempted the device from premarket notification;
12. The FDA listing number assigned to the device;
13. The Global Medical Device Nomenclature (GMDN) term or code for the device; and
14. The total number of individual devices contained in the device package.

2. Rejection, removal or correction

a. FDA rejection or removal of submitted information

If you submit device identification data that: does not conform with UDI requirements; concerns a device or combination product that requires, but does not have premarket approval, licensure or clearance; concerns a device that is neither manufactured nor in interstate commerce in the United States; the product is not a device or does not contain a device; or concerns a device that we have banned, we may reject or delete that information from GUDID. We may also reject or remove any device identification data if we have suspended the accreditation of the IA that you use. This does not apply if the IA relinquishes or does not renew its accreditation. This is explained further in Section V.C.

b. Correction (21 CFR 830.350)

We may notify you and delete or correct any information submitted to the GUDID that appears to be incorrect or potentially misleading. You must provide corrected information, or explain why the information is correct, within 30 days from receipt of our notice.

E. Exceptions and Alternatives to the UDI Requirement

1. General Exceptions (21 CFR 801.30)

The following types of devices are excepted from the UDI labeling requirement in 21 CFR 801.20.

Description of Device Category	Exception	Additional Information
Finished Device	Manufactured and labeled prior to the compliance date established by FDA for Section 801.20 regarding the device.	This exception expires with regard to a particular device 3 years after the compliance date established by FDA for the device.
Class I GMP Exempt Device	Class I devices, exempted by FDA from the good manufacturing practice requirements of part 820 of this chapter, exclusive of any continuing requirement for recordkeeping under Sections 820.180 and 820.198.	
Individual Single-Use Devices	Distributed together all of a single version or model in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution.	The device package containing these individual devices is not excepted from UDI labeling requirements.
Device used solely for research, teaching, or chemical analysis	Not intended for clinical use.	
Custom Device	As defined in Section 812.3.[4]	
Investigational Device	As defined in Section 812.3.[5]	

[4] As per § 812.3(b), *custom device* means a device that:
(1) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
(2) Is not generally available to, or generally used by, other physicians or dentists;
(3) Is not generally available in finished form for purchase or for dispensing upon prescription;
(4) Is not offered for commercial distribution through labeling or advertising; and
(5) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

[5] As per § 812.3(g), *investigational device* means a device, including a transitional device, which is the object of an investigation.

Veterinary Medical Device	Not intended for use in the diagnosis of disease or other conditions in man, in the cure, mitigation, treatment, or prevention of disease in man, or intended to affect the structure or any function of the body of man.	
Exported Device	Intended for export from the United States.	
Strategic National Stockpile	Held by the Strategic National Stockpile and granted an exception or alternative under Section 801.128(f)(2).	
Performance standard established by FDA under section 514(b) of the Federal Food, Drug, and Cosmetic Act	This exception applies if the performance standard established by FDA provides an exception from the requirement of Section 801.20 or includes an exception from the requirement of section 801.20 within the scope of that recognition.	
Packaged device within the immediate container of a combination product or convenience kit	Label of the combination product or convenience kit bears a UDI.	
Combination Product	Bears a National Drug Code (NDC) number on its label.	Each device constituent of a combination product, other than one described by Section 3.2(e)(1), must bear a UDI.[6]
Shipping Container	UDI not required to be placed on shipping containers.	

[6] 21 CFR 3.2(e)(1) provides that a *combination product* includes:
(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

2. Requesting a Specific Exception or Alternative (21 CFR 801.55)

You may submit a request for a specific exception from or alternative to the UDI labeling requirement or any other requirement of the UDI Rule.

The written request must:

1. Identify the device or devices that would be subject to the exception or alternative;
2. Identify the provisions of 21 CFR Part 801 Subpart B that are the subject of the request for an exception or alternative;
3. If requesting an:

Exception	Explain why you believe the requirements of 21 CFR Part 801 Subpart B are not technologically feasible
Alternative	Describe the alternative and explain why it would provide for more accurate, precise, or rapid device identification than the requirements of 21 CFR Part 801 Subpart B or how the alternative would better ensure the safety or effectiveness of the device subject to the alternative;

4. Provide, if you know, the number of labelers and the number of the devices that would be affected were we to grant the requested exception or alternative; and
5. Provide other information that we request to clarify the scope and effects of the requested exception or alternative.

Send the written request for an exception or alternative to:

Device regulated by:	**Email**	**Mailing Address**
Center for Biologics Evaluation and Research (CBER)	cberudirequests@fda.hhs.gov	Center for Biologics Evaluation and Research, FDA, Document Control Center, 10903 New Hampshire Avenue, Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002
All other devices	udi@fda.hhs.gov	UDI Regulatory Policy Support, CDRH, FDA, Bldg. 66, Rm. 3303, 10903 New Hampshire Avenue, Silver Spring, MD 20993-002

F. Modifications to other 21 CFR Provisions

The UDI Rule modifies additional sections of 21 CFR so that other 21 CFR provisions remain consistent with the provisions, definitions, and language of the UDI Rule. The below chart describes modifications made by the UDI Rule to other CFR sections that have not otherwise been mentioned in this Guidance.

The UDI requirements that affect other sections of 21 CFR went into effect on December 23, 2013. But there is no practical effect until the other provisions must be complied with. (See Section VI - Compliance Dates). For example, the amendments to Parts 820 and 822 will have no practical effect until September 24, 2014, when class III devices become subject to UDI labeling requirements.

Section Modified	Modification
803.32	User facilities must include the UDI on the device label or on the device package in individual adverse event report submissions.
803.33	User facility must submit in annual reports the UDI that appears on the device label or device package.
803.42	Importers must include the UDI on the device label or on the device package in individual adverse event report submissions.
803.52	Manufacturers must include the UDI on the device label or on the device package in individual adverse event report submissions.
806.10	The manufacturer or importer must include on reports of corrections and removals: the UDI that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
806.20	Records of corrections and removals not required to be reported to FDA shall contain the UDI, or the device identifier, UPC, model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.
810.10	FDA will include the UDI that appears on the device label or on the device package in its cease distribution and notification order.
814.84	The holder of an approved pre-market approval shall identify in its periodic report each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report.
820.120	Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct UDI or UPC, expiration date, control number, storage instructions, handling instructions, and any additional processing instructions.
820.184	Device history records must include any UDI or UPC, and any other device identification(s) and control number(s) used.
820.198	Manufacturers must include in their complaint files any UDI or UPC, and any other device identification(s) and control number(s) used.
820.200	Service reports that represent an event that must be reported to FDA must include any UDI or UPC and any other device identification(s) and control number(s) used.
821.25	A manufacturer of a tracked device must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of these devices.
821.30	Persons other than device manufacturers and distributors must include the UDI, lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device.
822.9	Class II and III device manufacturers required to conduct postmarket surveillance must include both premarket application/submission number and device identifiers in the postmarket surveillance plan submission.

VI. Compliance Dates

Compliance Dates for UDI Implementation

	Finished devices manufactured and labeled prior to the compliance date established by FDA	
Device	**Label/GUDID/Date Format**	**Permanent UDI (When Required)[3]**
Class III (including class III LS/LS)[1] Devices licensed under the PHS Act	September 24, 2014	Class III LS/LS devices must bear a permanent UDI by September 24, 2015 All other class III devices must bear a permanent UDI by September 24, 2016
I/LS/LS[2] (class II, class I & unclassified)	September 24, 2015	September 24, 2015
Class II	September 24, 2016	September 24, 2018
Class I or unclassified	September 24, 2018	September 24, 2020

[1]LS/LS = life-supporting or life-sustaining
[2]I/LS/LS = implantable, life-supporting, or life-sustaining
[3]Permanent UDI requirements apply to products that are intended to be used more than once and intended to be reprocessed before each use. Direct mark compliance dates are in addition to label/GUDID/date format compliance dates.