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Unique Device Identification: Direct Marking of Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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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: 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 at 1-800-835-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
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Preface

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CBER

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 20993-0002, 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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Unique Device Identification: Direct Marking of Devices

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 staff responsible for this guidance as listed on the title page.

I. Introduction

When finalized, this draft document will assist industry, particularly labelers, as defined under 21 CFR 801.3, and FDA staff in understanding FDA's requirements for direct marking of devices for unique device identification purposes. Under 21 CFR 801.45, "[a] device that must bear a unique device identifier (UDI) on its label must also bear a permanent marking providing the UDI on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use." This draft guidance defines some terms used in the Agency's regulations pertaining to the UDI direct marking requirements, including how FDA interprets the term "reprocessed" as used in 21 CFR 801.45. For additional background on the UDI system, see the UDI System Final Rule, published on September 24, 2013 (78 FR 58786) (the UDI Rule).

Throughout this draft guidance document, the terms "we," "us" and "our" refer to FDA staff from Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). "You" and "your" refers to the labeler, as that term is defined in 21 CFR 801.3.

FDA's guidance documents, including this draft 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 guidances means that something is suggested or recommended, but not required.

II. Background

Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), 121 Stat. 854, and Section 614 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), 126 Stat. 1061, amended the Federal Food, Drug, and Cosmetic Act to add Section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices along with implementation timeframes for certain medical devices. The UDI Rule, establishing the unique device identification system, was published on September 24, 2013 (78 FR 58786) (the UDI Rule). It requires that the label and each device package of a medical device distributed in the United States bear a unique device identifier (UDI), unless an exception or alternative applies. The UDI regulations also require specified information to be submitted to FDA's Global Unique Device Identification Database (GUDID). Most of the information submitted to GUDID is available to the public through AccessGUDID.

The UDI system seeks to improve the identification of medical devices by making it possible to rapidly and definitively identify a device and some key attributes that affect its safe and effective use. This will facilitate more accurate reporting of adverse events by making it easier to pinpoint the device at issue in the submitted report. FDA, health care providers, and industry may then more rapidly and precisely extract useful information from adverse event reports and thereby gain a better understanding of the underlying problems and improve the ability to take appropriate and better-focused corrective action.

The UDI regulation at 21 CFR 801.45 requires a UDI direct marking on a device if the device is intended to be used more than once and intended to be reprocessed before each use. This requirement applies to class I, II and III devices, with certain exceptions. As explained in the preamble of the UDI Rule, direct marking requirements apply to devices that are intended to be used for months or years, sometimes many years. Because such devices are intended to be reprocessed and reused, they will inevitably be separated from their original labels and device packages. Direct marking helps to ensure the adequate identification of such devices through their distribution and use. However, the UDI Rule does not define "intended to be used more than once" or "reprocessed". FDA's interpretation of these terms as they are used in 21 CFR 801.45 is included in this document.

III. Questions and Answers

A. Direct Marking

1. What is direct marking?

Direct marking, for purposes of UDI requirements, is affixing a UDI permanently on the device itself.

2. Which devices are required to be directly marked?

Under 21 CFR 801.45(a), if a UDI is required on a device label, that device is also required to have a UDI permanently affixed to the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. This requirement applies to all device classes, except class I devices that bear a Universal Product Code (UPC) on their label and device packages, as provided in 21 CFR 801.40(d). As explained in the preamble of the UDI Rule, direct marking requirements apply to devices that are intended to be used for months or years, sometimes many years. Because such devices are intended to be reprocessed and reused, they will inevitably be separated from their original labels and device packages. Direct marking best assures the adequate identification of such devices.

3. What are the compliance dates for the direct marking requirements?

The compliance date, i.e., the date by which you must comply with the UDI direct marking requirements, is based on the device category as shown below and also on the UDI webpage: www.fda.gov/udi. The compliance dates for UDI direct marking requirements are listed below:

Direct Marking Compliance Date	Category of Device Intended to be Reused and Reprocessed
9/24/2015	Life-sustaining and life-supporting devices, regardless of device class[1]
9/24/2016	Class III devices and devices licensed under the Public Health Service Act
9/24/2018	Class II devices
9/24/2020	Class I devices and unclassified devices

4. What about a device that has been manufactured and labeled prior to its UDI compliance date?

Under 21 CFR 801.30(a)(1), a finished device manufactured and labeled prior to its compliance date for 21 CFR 801.20 is excepted from UDI labeling requirements until three years after the UDI compliance date for 21 CFR 801.20 for that particular device. Because direct marking requirements and data submission requirements are tied to the UDI labeling requirement at 21 CFR 801.20, the exception at 21 CFR 801.30(a)(1) applies to these

[1] See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm, UDI Resources for list.

requirements as well. For example, the compliance date for 21 CFR 801.20 for class III devices was September 24, 2014. Thus, an individual Class III device requiring direct marking that was manufactured and labeled on May 1, 2014, would not be required to be in compliance with UDI labeling, direct marking, or GUDID data submission requirements until September 24, 2017.

5. Does FDA specify a method to directly mark a device?

No. We expect the permanent UDI to comply with the requirements of 21 CFR 801.45(b) and (c) and last throughout the expected use life of the device, taking into account expected usage and reprocessing. Possible methods to directly mark a device with a UDI include etching, attaching a permanent plaque to durable equipment, or affixing a permanent tag such as a radio frequency identification (RFID) tag to the device. However, we do not specify any particular approach to directly mark devices, because it would be difficult to account for the wide variety of existing devices, use conditions, and reprocessing methods for these devices. Moreover, technological advancements may lead to change in device usage, methods of device marking, and reprocessing procedures. The labeler should determine the appropriate method to provide such a marking on the device itself**.**

6. For currently legally marketed devices, does affixing a permanent marking on the device to comply with UDI requirements require a premarket approval (PMA) supplement, a biologics license application (BLA) supplement, or a new premarket notification (510(k)) submission?

For devices classified through the de novo process or cleared in a 510(k) submission, we expect you to conduct analysis and/or testing to determine whether direct marking could significantly affect the safety or effectiveness of the device and to document the basis for your determination in the design history file. See 21 CFR 807.81(a)(3)(i). If any type of direct marking would interfere with the safety or effectiveness of your device, your device would qualify for the exception under 21 CFR 801.45(d)(1), and we encourage you to make use of this exception if it applies. If any type of direct marking would interfere with the safety or effectiveness of your device but you wish to directly mark your device, thereby not making use of this exception, clearance of a new 510(k) submission would generally be required, since we anticipate that a direct marking that would interfere with the safety or effectiveness of a device under 21 CFR 801.45(d)(1) also could significantly affect the safety or effectiveness of the device under 21 CFR 807.81(a)(3)(i). When in doubt, we encourage you to contact the CDRH or CBER review division relevant for your device to discuss your specific situation.

For devices approved in a PMA or BLA, if adding a UDI direct marking would affect the safety or effectiveness of the device, this will require a supplemental PMA or BLA. 21 CFR814.39. FDA believes this will typically be the case. If, however, adding a UDI direct marking to a device approved in a PMA or BLA would not affect safety and effectiveness, no

supplement would be required, but this change should be reported in an annual report. For PMA devices, please review the guidance, Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision at http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089274.htm. For BLA devices, please review the guidance, Changes to an Approved Application: Biological Products at http://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/blood/ucm170166.pdf .

7. If a PMA supplement, BLA supplement, or new 510(k) is required as a result of UDI direct marking requirements, are user fees also required?

Yes. You must pay the applicable user fee, if any, if you submit a PMA supplement, a BLA supplement or a new 510(k) submission. There are no user fee waivers for submitting a PMA supplement, a BLA supplement, or a new 510(k) submission as a result of UDI direct marking requirements. However, FDA encourages you to bundle your required submissions rather than submit individually, which will reduce both administrative and user fee burdens. See FDA guidance entitled "Bundling Multiple Devices or Multiple Indications in a Single Submission" issued on June 22, 2007 (Bundling Guidance).

8. What are the GUDID data submission requirements for devices that must be directly marked with a UDI?

Under 21 CFR 801.40(b), each UDI must include a device identifier (DI) segment. The UDI on the device's label may be the same or different from the UDI directly marked on the device (see section III.B.2), which means two different DIs may be associated with the same device at the base package level. For the purposes of this draft guidance, the DI on a device's label is referred to as the primary DI, and the DI that is directly marked on a device is referred to as the direct-mark DI (DM-DI).

The UDI regulation at 21 CFR 830.310 sets forth the information submission requirements for all devices required to bear a UDI on their label. Each primary DI must be submitted to GUDID, as required by 21 CFR 830.310(b)(1). If the DI and the DM-DI are the same, no additional information needs to be submitted to GUDID. If the DI and the DM-DI are different, the labeler must submit the DM-DI. 21 CFR 830.310(b)(3). In this case, the labeler should check the box "DM DI Different from Primary DI" and enter the DM-DI Number as part of its GUDID submission. As stated in section III.A.9., we expect the records required under 21 CFR 830.360 to indicate whether DM-DI is the same or different from the primary DI.

If you are applying one of the exceptions listed in 21 CFR 801.45(d), you should check the box "Device Subject to Direct Marking (DM), but Exempt." We outline the general exceptions to the UDI direct marking requirements in section III.D of this draft guidance.

9. What are the recordkeeping requirements for devices that must be directly marked with a UDI?

The record requirements under 21 CFR 830.360 apply to UDI direct markings as well as UDIs placed on the device label and device packages. We expect that the records will indicate whether a device is directly marked and whether the DM-DI is the same or different from the primary DI. The records do not need to list each individual UDI [DI plus production identifier (PI)] separately. Rather, the labeler should maintain records for each DI with its associated range of PIs. The records should be regularly updated to reflect additional PIs associated with each DI. If your device falls within one of the exceptions from direct marking under 21 CFR 801.45(d) and you decide to make use of such, you are required to keep records supporting this decision in the design history file (see 21 CFR 801.45(e)). If you determine any type of direct marking would interfere with the safety and effectiveness of the device (21 CFR 801.45(d)(1)), we expect the rationale that supports your decision to be scientifically justified by analysis and/or testing. If the device cannot be directly marked because it is not technologically feasible (21 CFR 801.45(d)(2)), we expect you to document the rationale for the technological infeasibility in the design history file.

10. May a labeler voluntarily comply with direct marking requirements?

Yes. We encourage affixing a UDI permanently on devices even when not required. If a labeler of a device that is not required to bear a UDI under 21 CFR 801.45 directly marks such a device voluntarily, or before the compliance date of UDI direct marking requirements, GUDID data submission requirements applicable to UDI direct marking would also be voluntary. Please see sections III.A.6. and 7. above regarding potential impact on safety and effectiveness and the potential requirement for an additional premarket submission in conjunction with applying a UDI direct marking to a currently marketed device.

B. UDI Format

1. Is the full UDI required to be directly marked on the device?

Yes. A UDI direct marking must be either identical to the UDI that appears on the label of the device, or a different UDI used to distinguish the unpackaged device from any device package containing the device (21 CFR 801.45(b)). Either way, unless excepted, the full UDI must be directly marked, including the device identifier (DI) and any required production identifiers (PI). See 21 CFR 801.40(b) and 801.45. Note that production identifiers are not

required in UDIs of class I devices. 21 CFR 801.30(d). Also note that class I devices that bear a Universal Product Code (UPC) on their label and device packages are not required to comply with UDI direct marking requirements. See 21 CFR 801.40(d).

2. Does the UDI directly marked on the device need to be identical to the UDI on the device label?

No. Under 21 CR 801.45(b), the labeler may choose to directly mark the device with a UDI identical to the UDI that appears on the label of the device, or with a different UDI to distinguish the unpackaged device from any device package containing the device.

3. For a UDI direct marking, are both the plain text and AIDC forms required?

No. Unlike the UDI on labels and packages, under 21 CFR 801.45(c), when a device must bear a UDI direct marking, the UDI may be provided through either or both of the following: (1) easily readable plain-text or (2) automatic identification and data capture (AIDC) technology or any alternative technology that will provide the UDI of the device on demand. Both the plain text and the AIDC forms of the directly marked UDI should adhere to the UDI format specified by the FDA-Accredited Issuing Agency. See 21 CFR 830.20 and "UDI Formats by FDA-Accredited Issuing Agency (May 7, 2014)" (UDI Formats).

4. If the UDI that appears on the device label changes, must the directly marked UDI be replaced?

No. Under 21 CFR 801.45(d)(4), once a device has been marked in compliance with the UDI direct marking requirements, there is no requirement to replace the UDI direct marking even if the UDI that appears on the label changes.

C. Reprocessing

1. How is "intended to be used more than once" defined?

For the purposes of the UDI direct marking requirements, under 21 CFR 801.45, "intended to be used more than once" means intended for repeated uses on or by different patients, for example, where a device is cleared or approved and labeled for repeated uses on or by different patients.

2. What does FDA consider "reprocessed" for the purpose of direct marking?

Reprocessing is defined as validated processes used to render a medical device, which has been previously used or contaminated, fit for a subsequent use. See "Reprocessing Medical

Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff" issued on March 17, 2015 (Reprocessing Guidance). Reprocessing is generally intended to remove blood, tissue, biological debris, and other contaminants and to inactivate infectious microbes so that devices are safe for the next patient.

For purposes of UDI direct marking requirements, we consider a device that is intended to be cleaned and either sterilized or disinfected before each use to be intended to be reprocessed. If a device is intended only to be cleaned between uses by different patients, this would not be considered reprocessing for the purposes of the UDI direct marking requirements. If the device is intended to be used more than once on or by the same patient, and not on or by different patients, the device does not need to be directly marked with a UDI.

D. Exceptions to Direct Marking

1. What exceptions are there to the UDI direct marking requirements?

There are four direct marking exceptions outlined in 21 CFR 801.45(d). The requirement of 21 CFR 801.45(a) does not apply to any device that meets any of the following criteria:

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

A "single use device" means a device that is intended for one use, or on a single patient during a single procedure. 21 U.S.C. 321(ll). We interpret 21 CFR 801.45(d)(3) to mean that the UDI direct marking requirements do not apply to a device that the original labeler (as defined in 21 CFR 801.3) intends for one use, or use on a single patient during a single procedure, even if, subsequent to its initial use, the device is subjected to additional processing and manufacturing for the purpose of an additional single use on another patient. However, such reuse of a single use device would generally require additional clearance or approval unless 510(k)-exempt,[2] as well as compliance with general UDI labeling and data submission requirements by the entity performing the additional processing and manufacturing for the purpose of an additional single use. In contrast, for purposes of UDI

[2] See 21 U.S.C. 360(o) and "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434.htm) regarding 510(k) submissions for reprocessed single-use devices.

direct marking requirements under 21 CFR 801.45, a device intended for repeated use on or by different patients is "intended to be used more than once" and is thus subject to UDI direct marking requirements (see section III.C.1).

Please note that a reprocessed and/or relabeled single use device must comply with the general UDI labeling and data submission requirements. See definition of "labeler" under 21 CFR 801.3 and requirements for when a device is relabeled under 21 CFR 830.60.

2. Does a non-UDI direct marking (such as the name of the company or part or catalog number) on a device itself meet the UDI direct marking requirements?

No. The name of the company or part/catalog number only does not meet the UDI direct marking requirements under 21 CFR 801.45. If your device design with a non-UDI direct marking has been cleared or approved, we are unlikely to find merit in a justification for an exception under 21 CFR 801.45(d)(1) that direct marking would interfere with the safety or effectiveness of the device. In addition, lack of space because non-UDI direct marking has taken up the otherwise available space for a UDI direct marking will typically not be sufficient justification for an exception under 21 CFR 801.45(d)(2) that the device cannot be directly marked because it is not technologically feasible.

3. What is the process for making use of a 21 CFR 801.45(d) exception from a direct marking requirement?

As discussed in III.A.9., under 21 CFR 801.45(e), a labeler who decides that an exception under 21 CFR 801.45(d) applies to its device must document the basis of that decision in the design history file required by 21 CFR 820.30(j). As explained in III.A.8., in your GUDID submission, you should check the box "Device Subject to Direct Marking (DM), but Exempt."

4. What is the process for requesting a specific alternative to direct marking? How do I request an exception from or alternative to the direct marking requirements?

The UDI regulation at 21 CFR 801.55 outlines the process for requesting a specific alternative to any UDI requirement, including direct marking, by submitting a request to FDA. Under 21 CFR 801.55(c), FDA may grant an alternative to UDI direct marking or any other UDI labeling requirement, if we determine that:

(a) An alternative would provide for more accurate, precise, or rapid device identification; or
(b) An alternative would better ensure the safety or effectiveness of the device.

Please note that there is no reason to submit a 21 CFR 801.55 request for exception from UDI direct marking requirements if any exception under 21 CFR 801.45(d) is applicable. Requests

for the current instructions on requesting an alternative may be submitted using the online form by clicking the FDA UDI Help Desk link at www.fda.gov/udi.