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Unique Device Identification: Direct Marking of Devices

Guidance for Industry and Food and Drug Administration Staff

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Preface

Public Comment

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Unique Device Identification: Direct Marking of Devices

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 or Office responsible for this guidance as listed on the title page.

I. Introduction

This 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 guidance defines some terms used in the Agency's regulations pertaining to the UDI direct marking requirements, including how FDA interprets the term "intended to be reprocessed" as used in 21 CFR 801.45. For additional background on the UDI system, see the Unique Device Identification System Final Rule, published on September 24, 2013 (78 FR 58786) (the UDI Rule - https://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf).

Throughout this guidance document, the terms "we," "us" and "our" refer to FDA staff from the 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 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

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 (FDASIA), 126 Stat. 1061, amended the Federal Food, Drug, and Cosmetic Act (FD&C 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). It requires that the label and each device package of a medical device distributed in the United States bear a 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 at https://accessgudid.nlm.nih.gov/.

The UDI system seeks to improve the identification of medical devices by making it possible to rapidly and definitively identify a device and certain 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.

For devices required to bear a UDI on their device label, 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. 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 "intended to be 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 helps to ensure 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 labelers must comply with the UDI direct marking requirements, unless an exception or alternative applies, is based on the device category as shown below. The compliance dates for UDI direct marking requirements

are listed below and also on the UDI webpage[1]:

Direct Mark Compliance Date	Category of Device Intended to be Reused and Reprocessed
9/24/2015	Life-sustaining and life-supporting devices, regardless of device class
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 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 GUDID 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 requirements as well.

For devices intended to be used more than once and intended to be reprocessed before each use, the expiration of the three-year exception under 21 CFR 803.30(a)(1) is still based on the compliance date for UDI labeling requirements under 21 CFR 801.20, not the direct marking compliance date. For example, the compliance date for 21 CFR 801.20 for class II devices that are not implantable, life-supporting, or life-sustaining was September 24, 2016. Thus, an individual class II device manufactured and labeled on May 1, 2016, that is not implantable, life-supporting, or life-sustaining and that requires direct marking, would not be required to be in compliance with UDI labeling, GUDID data submission, or direct marking requirements until September 24, 2019.

FDA recognizes that some devices are consigned or loaned to hospitals or other healthcare facilities prior to the applicable UDI compliance date for 21 CFR 801.20 or are with a sales

[1] See https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIRequirements/default.htm.

representative in the field pending sale prior to that UDI compliance date. To the extent those devices are required to comply with UDI regulatory requirements for labeling under 21 CFR 801.20, direct marking under 21 CFR 801.45, or date format requirements under 21 CFR 801.18, FDA does not intend to enforce compliance with such requirements for those devices.

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

No. We expect the direct mark UDI to comply with the requirements of 21 CFR 801.45(b) and (c) and last throughout the expected service life of the device, taking into account expected usage and reprocessing according to the instructions of the manufacturer. 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. In some cases, particularly with certain durable equipment, a labeler will attach to the device hardware exterior a sticker or some other item that displays information and is designed to last the expected service life of the device. If this item bears the UDI in accordance with 21 CFR 801.45(b) and (c), you have fulfilled the requirements of 21 CFR 801.45.

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?

The FDA expects labelers to conduct analysis and/or testing to determine the effect of direct marking on the safety and effectiveness of the device and to document the basis for such determination in the design history file (DHF). If any type of direct marking would interfere with the safety or effectiveness of the device, the device would qualify for the exception under 21 CFR 801.45(d)(1), and FDA encourages labelers to make use of this exception if it applies.

For devices granted marketing authorization through the De Novo classification process or cleared in a 510(k) submission, if any type of direct marking would interfere with the safety or effectiveness of the device but the labeler still wishes to directly mark the device, thereby not making use of the exception under 21 CFR 801.45(d)(1), clearance of a new 510(k)

submission would likely be required, since FDA anticipates that a direct marking that would interfere with the safety or effectiveness of a device for purposes of 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, FDA encourages labelers to contact the CDRH or CBER review division relevant to the device to discuss the 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 typically require a PMA or BLA supplement under 21 CFR 814.39 or 601.12. If, however, adding a UDI direct marking to a device approved in a PMA or BLA would not be expected to affect safety and effectiveness, no supplement would be required, but the basis for your determination should be documented, and 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 – (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089731.htm).

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

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. If a device is required to be directly marked, additional data submission to GUDID may be required. Under 21 CFR 830.310(b)(1), the device identifier (DI)[2] portion of the UDI assigned to the version or model of the device must be submitted to GUDID. The DI that must be submitted under 21 CFR 830.310(b)(1) is the DI included in the lowest level of device packaging required to include the full UDI. We refer to this as the "Primary DI" for purposes of this guidance. In addition, if the Primary DI and the DI of the direct mark UDI are different, you need to indicate this in GUDID per 21 CFR 830.310(b)(3).[3] However, if the two DIs are identical, no additional information needs to be submitted to GUDID.

If you are applying one of the exceptions listed in 21 CFR 801.45(d), you should indicate in GUDID that the device is subject to direct marking but excepted. We outline the general exceptions to the UDI direct marking requirements in section III.D of this guidance.

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

The recordkeeping requirements under 21 CFR 830.360 apply to the UDI on the device label, the UDIs on the packages, and the direct mark UDI. Labelers are required to retain, and make available to FDA upon request, records showing all UDIs used to identify devices that must bear a UDI on their label. See 21 CFR 830.360(a). FDA expects that the records will indicate whether a device is directly marked and, if so, whether the direct mark DI is the same as or different from the primary DI. The records should be updated when changes to the production identifiers (PIs) are made, in order to reflect all PIs currently associated with each DI. Further, the Device Master Record (DMR) must include, or refer to the location of, the DI for the particular version or model of the device, as well as the associated types of PIs (i.e., lot or batch, serial number, expiration date, manufacturing date, distinct identification code) included in the UDIs for that particular version or

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[2] A unique device identifier is composed of a device identifier and a production identifier, as defined in 21 CFR 801.3.

[3] For additional information, see Global Unique Device Identification Database (GUDID): Guidance for Industry and FDA Staff (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf)

model of the device. See 21 CFR 820.181. The DMR does not need to contain the actual PIs. By contrast, the Device History Record (DHR) must include, or refer to the location of, the full UDI (DI and PIs) used to identify the device. See 21 CFR 820.184.

If a labeler's device falls within one of the exceptions from direct marking under 21 CFR 801.45(d) and the labeler decides to make use of such exception, the labeler is required to keep records supporting this decision in the DHF (see 21 CFR 801.45(e)). If the labeler determines any type of direct marking would interfere with the safety or effectiveness of the device (21 CFR 801.45(d)(1)), FDA expects the rationale that supports the decision to be scientifically justified by analysis and/or testing and to be documented in the DHF. If the device cannot be directly marked because it is not technologically feasible (21 CFR 801.45(d)(2)), FDA expects the labeler to document the rationale for the technological infeasibility in the DHF. Because it is expected that direct marking technology will advance over time, exceptions under 21 CFR 801.45(d)(1) and 21 CFR 801.45(d)(2) may lose their applicability over time and thus labelers should periodically reassess their use of those exceptions.

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

Yes. FDA encourages affixing a UDI permanently on devices even when not required. If a labeler of a device that is not required to bear a UDI as a permanent marking under 21 CFR 801.45 directly marks such a device voluntarily, or marks it before the compliance date of UDI direct marking requirements, GUDID data submission requirements applicable to UDI direct marking would also be voluntary but encouraged. (Note that such GUDID data submission requirements would no longer be voluntary as of the compliance date for UDI direct marking requirements). 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. In general, UDI direct marking must include both the DI and PI portions of the UDI See 21 CFR 801.40(b) and 801.45. Note that PIs are not required in UDIs of class I devices per 21 CFR 801.30(d). Also note that class I devices that bear a 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 CFR 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. As explained in the preamble to the UDI Rule, the direct mark must provide the full UDI, including all the production identifiers that appear on the device label (78 FR 58804). However, in situations where a production identifier (e.g., the lot number that appears on the device label) was unknown at the time a device was directly marked during the manufacturing process, FDA does not intend to enforce the requirement that the UDI directly marked on the device include that production identifier.

3. For a UDI direct marking, are both the easily readable 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. This permits flexibility given the wide disparity in the physical characteristics of medical devices. In deciding whether to use the easily readable plain-text or the AIDC form or both forms of the UDI for direct marking, labelers should consider factors such as technological feasibility, efficiency for the end user and risk of human error. Both the easily readable 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 (January 27, 2017)" (UDI Formats - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/UCM489869.pdf.)

4. If a labeler makes a change to a device that requires assigning a new UDI, must the labeler add to or replace the existing UDI direct mark?

No. Under 21 CFR 801.45(d)(4), a device that has previously been directly marked in compliance with 21 CFR 801.45(a) does not require a new or additional UDI direct mark. However, regardless of whether the device is directly marked with a UDI, whenever there

is a change to the device that results in a new version or model of the device, a new DI must be assigned to the device. See 21 CFR 830.50(a). That changed device must bear a UDI containing that new DI on its label. See 21 CFR 801.20.

As noted above, for example, a labeler may attach to a device's exterior hardware a sticker, plaque, or other item that displays information (including the UDI) and fulfills UDI direct marking requirements under 801.45. If the labeler subsequently makes a change to that device in the field and the change results in a new version or model, 21 CFR 830.50(a) requires a new DI to be assigned to the modified device. Under 21 CFR 801.20, the label of the new version or model of the device must bear a UDI incorporating that new DI, unless an exception or alternative applies. One way to fulfill these requirements under 21 CFR 801.20 and 21 CFR 830.50 would be to replace the sticker, plaque, or other item on the device hardware with a similar item that bears the new UDI; the labeler could also request an exception or alternative.

C. Reprocessing

1. How is "intended to be used more than once" defined for purposes of UDI direct marking?

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, e.g., where a device is cleared or approved and labeled for repeated uses on or by different patients. If the device is intended to be used more than once on or by the same patient, and not on or by multiple patients, then the device does not need to be directly marked with a UDI.

2. What does FDA consider "intended to be reprocessed" for the purposes of UDI direct marking?

For purposes of UDI direct marking requirements, we consider a device intended to be reprocessed if it is intended to undergo high-level disinfection and/or sterilization before each use or between uses. This means that devices that are only intended to be cleaned and/or to undergo lower levels of disinfection without subsequent high-level disinfection[4] or

[4] For purposes of this guidance document, high-level disinfection is a lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores.

sterilization before each use or between uses are not required to be directly marked with a UDI under 21 CFR 801.45.

D. Exceptions to Direct Marking

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

There are four UDI 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. Section 201(ll) of the FD&C Act (21 U.S.C. 321(ll)). FDA interprets 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,[5] as well as compliance with general UDI labeling and GUDID 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 direct marking requirements under 21 CFR 801.45, a device intended for repeated use on or by different patients is "intended to be

[5] See section 510(o) of the FD&C Act (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.

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 GUDID 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 alone does not meet the UDI direct marking requirements under 21 CFR 801.45. If your device design has been cleared or approved with a non-UDI direct marking, a justification for an exception under 21 CFR 801.45(d)(1) or under 21 CFR 801.45(d)(2) should explain how the UDI direct marking and the non-UDI direct marking are relevantly different. For example, a justification for an exception under 21 CFR 801.45(d)(1) that UDI direct marking would interfere with the safety or effectiveness of the device would explain why the UDI direct mark is different than the non-UDI direct marks with respect to its effect on the safety and effectiveness of the device. In addition, while the presence of non-UDI direct marking will typically not be sufficient justification for an exception under 21 CFR 801.45(d)(2) on the grounds of limited space, non-UDI direct marking that takes up all available space and is required for patient safety could be a justification for an exception under 21 CFR 801.45(d)(1). For new devices, UDI direct marking requirements should be considered and/or incorporated at design inception.

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 DHF required by 21 CFR 820.30(j). As explained in III.A.8., in your GUDID data submission, you should indicate that the device is subject to direct marking but excepted.

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.