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Unique Device Identification: Direct Marking of Devices Final Guidance

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Agenda

- Background
- Scope
- Key changes from draft to final guidance
- Highlights from the guidance
- Questions

Background

- UDI Final Rule September 24, 2013 [78 FR 58786]
- Intent of the Unique Device Identification System is to adequately identify devices through distribution and use

Background

- Unique Device Identification System Requirements (unless an exception or alternative applies):
 - Device label and device packages must bear a unique device identifier (UDI).
 - Labeler must submit product information to the Global Unique Device Identification Database (GUDID).
 - UDI must be directly marked on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use.

Background

- Draft guidance published on June 26, 2015
- Questions in Notice of Availability
 - 1) Should the definition of “reprocessing” for purposes of UDI direct marking requirements include cleaning alone without subsequent disinfection and/or sterilization of the device?
 - 2) What public health benefits would be served by requiring a UDI direct marking to be affixed to devices intended to be reused for which reprocessing instructions include cleaning only and not disinfection and/or sterilization?
- Received 17 sets of comments
- Final guidance published on November 17, 2017

Scope of the Guidance

- Applies to devices required to bear a UDI on their label that are also:
 - Intended to be used more than once, and;
 - Intended to be reprocessed.
- Does not apply to implants, which are not required to be directly marked.

Key Changes from the Draft



- Narrows the definition of “intended to be reprocessed” for purposes of UDI direct marking
 - Draft guidance: we consider a device that is intended to be **cleaned and either sterilized or disinfected** before each use to be intended to be reprocessed.
 - Does not include a device intended only to be cleaned between uses.
 - Final guidance: 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.
 - Does not include a device intended only to be cleaned and/or to undergo lower levels of disinfection without subsequent high-level disinfection or sterilization before each use or between uses.



Key Changes from the Draft

Consigned or loaned devices

To the extent these devices are required to comply with UDI requirements, FDA does not intend to enforce compliance with labeling under 21 CFR 801.20, direct marking under 21 CFR 801.45, or date format requirements under 21 CFR 801.18, for:

- Devices consigned or loaned to hospitals or other health care facilities prior to the applicable UDI label compliance date.
- Devices with a sales representative in the field pending sale prior to the applicable UDI label compliance date.



Highlights: Compliance Dates

UDI 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**

** FDA issued a letter noting our intent to extend the UDI compliance dates for class I and unclassified devices. For more information see:

<https://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM561575.pdf>

Highlights: Format of the UDI



- The direct mark should include the device identifier (DI) and production identifier (PI) portions of the UDI (all PI that appear on the label). Exceptions:
 - Class I devices not required to include PI.
 - In situations where a PI 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 PI.
- The UDI directly marked on the device may be the same as the UDI on the label, or the labeler may choose a different UDI to distinguish the unpackaged device from any device package containing the device.



Highlights: Form of the UDI

- Unlike the UDI on labels and packages, the UDI direct mark may be provided through either or both:
 - 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.
- In deciding the form(s) of the UDI for direct marking, labelers should consider factors such as technological feasibility, efficiency for the end user and risk of human error



Highlights: Method of Marking

- We expect the direct mark UDI to last throughout the expected service life of the device, taking into account expected usage and reprocessing according to the instructions of the manufacturer.
- 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.
- Technological advancements may lead to change in device usage, methods of device marking, and reprocessing procedures.

Highlights: GUDID Data Submission

- The DI portion of the UDI assigned to the version or model of the device must be submitted to GUDID. This DI is the DI included on the lowest level of device packaging required to include the full UDI (“Primary DI”).
- If a device is required to be directly marked, additional data submission to GUDID may be required:
 - If the Primary DI and the DI of the direct mark UDI are different, you need to indicate this in GUDID. 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.

Highlights: Voluntary Marking



- If a device is not required to be directly marked with a UDI, FDA encourages voluntary direct marking, including voluntary GUDID data submission requirements applicable to UDI direct marking.

Highlights: Reuse

- For the purposes of the UDI direct marking requirements, "intended to be used more than once" means intended 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.

Highlights: Reprocessing

- For purposes of UDI direct marking, 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.
- Devices that are only intended to be cleaned and/or to undergo lower levels of disinfection without subsequent high-level disinfection or sterilization before each use or between uses are not required to be directly marked with a UDI.

Highlights: Exceptions

- Exceptions under 801.45(d):
 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 with a UDI under 21 CFR 801.45(a).

Highlights: Exception Documentation



- For a labeler to make use of an exception provided under 801.45(d):
 1. Basis of the decision must be documented in the Design History File (DHF);
 2. GUDID record for the device should indicate that the device is subject to direct marking but excepted;
 3. If the exception is based on technological infeasibility, plan for periodic reconsideration of applicability since the threshold for technological infeasibility may change over time with new technology.

Highlights: Non-UDI Markings



- The name of the company or part/catalog number alone does not meet the UDI direct marking requirements under 21 CFR 801.45.
- 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).

Highlights: Alternatives

- 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 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.



Questions?

FDA UDI Help Desk: www.fda.gov/udi

Subject: UDI Direct Mark Guidance

General questions about this webinar?

Contact Division of Industry and Consumer Education: DICE@fda.hhs.gov

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<http://www.fda.gov/training/cdrhlearn>

Under Heading: Unique Device Identification (UDI) System

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