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Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Document issued on October 14, 2021

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Preface

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Select Updates for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain 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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. Introduction

FDA has developed this draft guidance for labelers of class I devices to revise "Section III. Policy On Standard Date Formatting, UDI Labeling, and GUDID Submission Requirements for Class I and Unclassified Devices" of the guidance Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking,[1] ("2020 UDI Compliance Policy Guidance") that was issued on July 1, 2020. When this draft guidance is finalized, the updates in Section III of this draft guidance would supersede the recommendations in Section III of the 2020 UDI Compliance Policy Guidance. This draft guidance explains that there are certain class I devices for which FDA does not intend to enforce Global Unique Device Identification Database (GUDID) submission requirements under 21 CFR 830.300, and describes how a labeler of a class I device can determine whether its device is within the scope of this compliance policy.

FDA plans to incorporate the final version of this draft guidance into "Section III. Policy On Standard Date Formatting, UDI Labeling, and GUDID Submission Requirements for Class I and Unclassified Devices" of the 2020 UDI Compliance Policy Guidance. The remainder of the 2020

[1] Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and

UDI Compliance Policy Guidance, with the exception of technical edits for consistency with the newly amended Section III, would not be substantively changed.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, 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 and Rationale

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 a device's safe and effective use. A UDI generally consists of a device identifier and a production identifier.[2] However, for class I devices required to bear a UDI on their labels and device packages,[3] the UDI Rule does not require the UDI to include the production identifier (21 CFR 801.30(d)). In the preamble to the UDI Rule, we explain that FDA provides this limited exception "to avoid imposing significant burdens on lower risk devices, where the public health need for precise identification is less urgent than for moderate- and high-risk devices." (78 FR 58880, September 24, 2013). For class I devices, the UDI Rule provides that the Universal Product Code (UPC) may serve as the UDI (21 CFR 801.40(d)). As with the production identifier exception, this option was provided after weighing the public health benefit against the burden on industry with respect to these lower risk devices.

Many class I devices are sold directly to consumers over-the-counter in both brick-and-mortar and online stores (hereafter referred to as "consumer health products")[4]. Such products are typically labeled with a UPC, which is a barcode primarily used for scanning items at the point of sale. The UPC is used to identify products to a very granular level—such as where in stores the product is displayed, and whether the product has temporary promotional packaging—and the UPC for the same version or model of a device can change frequently.

The GUDID database is built from UDI system information[5] and provides a repository of device safety information for FDA. Most of the information submitted to GUDID is also available to the

[2] A device identifier is defined as a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and a production identifier is defined as a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: (i) The lot or batch within which a device was manufactured; (ii) The serial number of a specific device; (iii) The expiration date of a specific device; (iv) The date a specific device was manufactured; (v) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c) (21 CFR 801.3).

[3] "Label" and "device package" are defined at 21 CFR 801.3.

[4] For purposes of this guidance, "consumer health products" means 510(k)-exempt class I devices that are exclusively sold directly to consumers over-the-counter in both brick-and-mortar and online stores. These devices are typically labeled with a UPC, which may serve as the UDI for class I devices (21 CFR 801.40(d)).

[5] The GUDID contains the information required to satisfy the requirements of the UDI Rule. These include version or model number, certain safety characteristics, and identifying information regarding the labeler of the device.

public through AccessGUDID.[6] AccessGUDID enables healthcare providers and patients to obtain useful safety information on specific device models, such as sterility requirements and MRI compatibility information. AccessGUDID also provides downloadable data that facilitates analysis of devices by patient registries and other research efforts. GUDID data is also available on OpenFDA,[7] FDA's portal for publicly available data. OpenFDA allows public users to merge the GUDID device identification data with other FDA data sets, such as FDA Classification data.

As the various provisions of the UDI Rule have been implemented over the past several years, FDA has gained insight into the public health benefits and potential burdens of the UDI Rule requirements for class I devices. With respect to class I devices that are consumer health products, as described above, FDA believes that the entry of UDI data into GUDID, especially given the frequent changes to the UPCs serving as the UDIs for these devices, is burdensome to stakeholders. CDRH evaluated high-level medical device reporting and historical class I recall data for class I devices, as well as the benefits associated with GUDID submission. After analyzing the public health impact of this information, CDRH has a better understanding of the devices and device characteristics for which GUDID information is particularly useful in evaluating and improving device safety throughout a product lifecycle, as well as the ones for which GUDID information may be less important in this regard. Based on this analysis, FDA generally does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I consumer health product devices.

Class I devices that FDA does **not** consider to be consumer health products may pose greater risks to public health. These devices are typically used in healthcare settings and are often subject to additional regulatory controls, such as the requirement to submit premarket notification, devices restricted under 520(e) of the FD&C Act, and other requirements. For these devices, FDA has determined that submission of UDI data into GUDID is more important to help enable FDA and other stakeholders to evaluate and improve device safety throughout the product lifecycle[8]. Submission of UDI data into GUDID may also reduce medical errors and simplify the integration of device use information into data systems (see 78 FR 58786), which is more important for these devices. These devices are discussed further in Section III.B.2.

III. Revised Section III

A. Compliance Policy for Standard Date Formatting and UDI Labeling Requirements for Class I and Unclassified Devices

At this time, in light of the considerations discussed, FDA does not intend to enforce standard date formatting and UDI labeling requirements under 21 CFR 801.18, 21 CFR 801.20, and 21

[6] Available at: https://accessgudid.nlm.nih.gov/
[7] Available at: https://open.fda.gov/
[8] GUDID data may be used to facilitate recalls, medical device reporting, and in analysis of pre-market approval (PMA) annual reports and other FDA processes.

CFR 801.50 for class I and unclassified devices, other than implantable, life-supporting, and life-sustaining (I/LS/LS) devices,[9] before September 24, 2022.[10]

We note that, pursuant to 21 CFR 801.30(a)(1), a finished device manufactured and labeled prior to the compliance date established by FDA for 21 CFR 801.20 regarding that device is excepted from the requirement to bear a UDI for a period of three years after that compliance date. The compliance dates established in the preamble of the UDI Rule have not changed. Finished class I and unclassified devices, other than I/LS/LS devices, manufactured and labeled prior to September 24, 2018, are excepted from UDI labeling and GUDID data submission requirements for a period of three years after the established compliance date or until September 24, 2021 (see 21 CFR 801.30(a)(1)). However, FDA does not intend to enforce the requirements under 21 CFR 801.18, 801.20, and 801.50 for class I and unclassified devices, other than I/LS/LS devices, prior to September 24, 2022, regardless of the date they are manufactured and labeled.

B. Compliance Policy for GUDID Submission Requirements for Class I Devices

1. Class I Devices Considered Consumer Health Products

At this time, FDA does not intend to enforce the GUDID submission requirements under 21 CFR 830.300 for class I devices considered consumer health products that are required to bear a UDI on their labels and device packages. For purposes of this guidance, "consumer health products" means 510(k)-exempt class I devices that are exclusively sold directly to consumers over-the-counter in both brick-and-mortar and online stores. These devices are typically labeled with a UPC,[11] which may serve as the UDI for class I devices (21 CFR 801.40(d)).

2. Class I Devices Not Considered Consumer Healthcare Products by FDA

FDA has determined that class I devices that we do not consider consumer health products may pose greater risks to public health and, based on FDA's analysis, GUDID data may be more

[9] Section 519(f) of the FD&C Act requires implementation of FDA's unique device identification system regulations for I/LS/LS devices within two years of finalizing those regulations. For class I and unclassified I/LS/LS devices, the compliance date established by the FDA is September 24, 2015. See 78 FR at 58815-58816.

[10] This policy for standard date formatting and UDI labeling requirements under 21 CFR 801.18, 21 CFR 801.20, and 21 CFR 801.50 for class I and unclassified devices, other than I/LS/LS devices, remains the same as the policy in the 2020 UDI Compliance Policy Guidance, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and

[11] Class I devices that bear UPCs on their labels and device packages are deemed to meet all UDI labeling requirements of 21 CFR 801 subpart B (21 CFR 801.40(d)) and are not required to also bear a UDI, but may elect to do so.

important to monitoring the safety of these devices. These potentially higher risk devices are typically used in healthcare settings and are often subject to additional regulatory controls. Class I devices that fall into one or more of the categories described below are not considered consumer health products for purposes of this guidance and, therefore, do not fall within the enforcement policy described in this guidance regarding GUDID data submission requirements under 21 CFR 830.300. Other than class I I/LS/LS devices, which had a compliance date of September 24, 2015, class I devices that are required to bear a UDI on their labels and device packages generally remain subject to FDA's previously announced enforcement discretion policy until September 24, 2022.[12]

a. Class I Reserved Devices

The majority of class I devices are exempt from the 510(k) premarket notification process. However, "any class I device that is intended for a use which is of substantial importance in preventing impairment of human health… or … that presents a potential unreasonable risk of illness or injury" is not exempt from the 510(k) notification process. FD&C Act section 510(l)(1). These devices are typically referred to as "Class I Reserved Devices." More information about devices considered to be Class I Reserved Devices can be found on FDA's website.[13]

b. Restricted Devices

Under section 520(e) of the FD&C Act, FDA may by regulation require that a device be restricted to sale, distribution, or use only upon written or oral authorization by a practitioner licensed by law to administer or use such device (i.e., prescription use) or such other conditions as may be prescribed in such regulation. The regulations restricting the sale, distribution, or use of these devices are located in 21 CFR parts 801, subpart H, and for in vitro diagnostic devices, in part 809, subpart C.

c. Implantable Devices

"Implantable device" is defined at 21 CFR 801.3 as "a device that is intended to be placed in a surgically or naturally formed cavity of the human body" and "is regarded as an implantable device . . . only if it is intended to remain implanted continuously for a period of 30 days or more."

d. Life-Supporting or Life-Sustaining Devices

[12] See Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marking, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and

[13] Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/3151.cfm

"Life-supporting or life-sustaining device" is defined at 21 CFR 860.3(e) as a device that is "essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life." FDA recommends evaluating the characteristics of the device and looking to the device's intended use to determine whether a particular device is life-supporting or life-sustaining.

e. Certain Devices Distributed to Professional Healthcare Facilities and Intended for Use by Healthcare Professionals Only

This policy does not apply to devices that are distributed to professional healthcare facilities,[14] are intended for use by healthcare professionals only, and that are devices that are: (1) reusable or reprocessed,[15] including those that are non-sterile and sterilized on-site before use; or (2) intended for wound care.

C. Compliance Policy for GUDID Submission Requirements for Unclassified Devices

An unclassified device is a pre-amendments device type[16] for which a classification regulation has not been promulgated. Unclassified devices generally require submission of a 510(k) premarket notification. FDA has issued compliance policies related to certain unclassified devices.[17] For unclassified devices, other than I/LS/LS devices, (including those labeled prior to

[14] "Professional healthcare facility" is defined as any environment where personnel with medical training are continually available to oversee or administer the use of medical devices. This includes, but is not limited to, hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, physicians' offices, and outpatient treatment facilities; or a clinical laboratory. For more information, see Design Considerations for Devices Intended for Home Use: Guidance for Industry and Food and Drug Administration Staff, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-devices-intended-home-use. If a device is distributed to other types of facilities, such as grocery stores or online or brick-and-mortar pharmacies, in addition to professional healthcare facilities, it is still considered "distributed to professional healthcare facilities" for purposes of this guidance.

[15] For purposes of this guidance, consistent with FDA's guidance, Unique Device Identification: Direct Marking of Devices ("Direct Mark Guidance") we consider a device to be reusable if it is "intended to be used more than once," meaning that it is 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, it is not considered reusable for purposes of this guidance. Also consistent with the Direct Mark 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.

[16] A preamendments device type is one that was in commercial distribution before May 28, 1976, the date the Medical Device Amendments were signed into law.

[17] *See* Guidance for Industry and Food and Drug Administration Staff: Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements (Feb. 8, 2019), available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/intent-exempt-certain-unclassified-medical-devices-premarket-notification-requirements

September 24, 2018, that are subject to 21 CFR 801.30(a)(1)), FDA does not intend to enforce GUDID data submission requirements under 21 CFR 830.300 before September 24, 2022.[18]

[18] This policy for GUDID data submission requirements under 21 CFR 830.300 for unclassified devices, other than I/LS/LS devices, remains the same as the policy in the 2020 UDI Compliance Policy Guidance, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-policy-regarding-compliance-dates-class-i-and-unclassified-devices-and