Unique Device Identification: Convenience Kits

Guidance for Industry and Food and Drug Administration Staff

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For questions about this document regarding CDRH-regulated devices, contact the UDI Regulatory Policy Support, 301-796-5995, email: gudidsupport@fda.hhs.gov.

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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

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2015-D-4048. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Unique Device Identification: Convenience Kits

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

FDA's unique device identification system includes unique device identifier (UDI) labeling (21 CFR 801.20) and data submission requirements (21 CFR 830.300).[1] The unique device identification system regulations require that the label and device package of a device must bear a UDI, unless an exception or alternative applies. An exception is provided at 21 CFR 801.30(a)(11) for devices packaged within the immediate container of a convenience kit, if the label of the convenience kit bears a UDI.

This guidance describes FDA's interpretation of the definition of "convenience kit" at 21 CFR 801.3 and as used in 21 CFR 801.30(a)(11). This guidance does not apply to *in vitro* diagnostic (IVD) devices that are subject to the IVD labeling requirements under 21 CFR part 809, nor does it apply to combination products as defined in 21 CFR 3.2(e).

Terms clarified within this guidance apply only for purposes of this guidance document and the UDI regulations, and are not intended to be applied beyond the regulations and policies pertaining to the unique device identification system. This guidance does not define the term "convenience kit" for other regulatory purposes.[2] Further, this guidance does not suggest that

[1] The final rule establishing the unique device identification system was published on September 24, 2013 (78 FR 58786) (the "UDI Rule"). *See also* section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) and section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144), which added and amended section 519(f) of the FD&C Act (21 U.S.C. § 360i(f)).

[2] The term "convenience kit" as used in this guidance document is not applicable to the May 20, 1997, guidance entitled "Convenience Kits Interim Regulatory Guidance" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080216.htm). In

compliance with the UDI regulations eliminates the need to comply with any other applicable requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act or its implementing regulations.

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 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

The unique device identification system was established to adequately identify devices through distribution and use.[3] The unique device identification system regulations require that the label and each device package of every medical device distributed in the United States bear a UDI, unless an exception or alternative applies (21 CFR 801.20).

The term "convenience kit" is defined in 21 CFR 801.3 as "two or more different medical devices packaged together for the convenience of the user." Individual devices packaged within the immediate container of a convenience kit are excepted from the UDI labeling requirements of 21 CFR 801.20, provided that a UDI is on the label of the immediate container of the convenience kit (21 CFR 801.30(a)(11)). Convenience kits are themselves devices.[4,5]

Although FDA previously expressed thinking that medical procedure kits containing only devices are convenience kits,[6] FDA believes that this policy requires clarification for consistency with the objective of the unique device identification system.[7] For purposes of

addition, this guidance does not apply to a "medical convenience kit" as that term is described in clause xiii of 21 U.S.C. § 360eee(24)(B) or 21 U.S.C. § 353(e)(4)(M).

[3] *See* Footnote 1.

[4] FDA clarified in the UDI Rule that convenience kits are considered devices. *See* the UDI Rule at 78 FR 58792 ("Convenience kits are in wide use and are medical devices in their own right, apart from their constituent devices…[C]onvenience kits are by definition devices and therefore are required to meet UDI requirements.").

[5] If you are uncertain about whether your collection of two or more different devices meets the definition of a device at section 201(h) of the FD&C Act, 21 U.S.C. § 321(h), please contact CDRH's Premarket Notification (510(k)) Program at 510k_program@fda.hhs.gov or CBER's OCOD at ocod@fda.hhs.gov.

[6] *See* the UDI Rule at 78 FR 58800.

[7] The overarching objective of the unique device identification system regulations, as required by section 519(f) of the FD&C Act, is to provide a system to adequately identify medical devices through distribution and use. We interpret this to mean that the UDI should be able to identify a device through distribution up to and including the point at which the device is used by an end user. The UDI's function of identifying the device

the UDI regulations, FDA does not consider every medical procedure kit, nor every collection of two or more medical devices, to be a "convenience kit."

FDA recognizes that the interpretation of terms provided in this guidance may mean that fewer medical procedure kits are "convenience kits" for purposes of the UDI regulations, which may impact the assembly and packaging of medical procedure kits that are not "convenience kits." Nevertheless, FDA believes that the interpretation of the term "convenience kit" in this guidance document is appropriate. As for all devices, a labeler may request an exception from or alternative to a UDI requirement under 21 CFR 801.55.[8]

III. Convenience Kits

A. Clarification of Key Concepts

This section provides FDA's interpretation of, and explanatory information about, the terms below, for purposes of this guidance and the UDI regulations.

- **Convenience Kit**: A convenience kit is "two or more different medical devices packaged together for the convenience of the user" (21 CFR 801.3). FDA interprets this to mean a device that contains two or more different medical devices packaged together and intended to remain packaged together and not to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before being used by an end user.

- **Packaged together**: Packaged together means packed (e.g., wrapped or sealed) in a single container that is not intended to be unwrapped or unsealed before it is used by an end user.

- **End user**: The end user is the individual using the device on or on behalf of a patient, e.g., the patient, a caregiver, a healthcare practitioner, or a medical technologist.

- **Medical Procedure Kit:** A medical procedure kit typically consists of one or more medical devices, packaged together to facilitate a single surgical or medical procedure.[9] A medical procedure kit may be a convenience kit.

B. Examples

through distribution and use, among other benefits, facilitates rapid identification of adverse events and more efficient management of device recalls.

[8] For more information, *see* https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIExceptionsAlternativesandTimeExtensions/default.htm.

[9] *See* the UDI Rule at 78 FR 58800.

The following examples illustrate how FDA interprets "convenience kit" for purposes of FDA's unique device identification system requirements, including UDI labeling and data submission requirements.

Example 1: Retail first aid kit

A first aid kit[10] sold at retail that includes only devices—such as bandages, cold compresses, scissors, and an oral thermometer—packaged together is a convenience kit. It is a device that contains two or more different medical devices that are packaged together for the convenience of the user and intended to remain packaged together and not to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before being used by an end user. Therefore, the label of each individual device within the container is not required to bear a UDI, provided that a UDI is available on the label affixed to the immediate container of the kit.

After purchasing a first aid kit, the end user may choose to replenish devices or add more devices over time, rather than purchasing a new first aid kit. A labeler may choose to market individual devices separately to the end user. In such cases, the label and device package of the individual devices that may be used to replenish or augment the first aid kit must bear a UDI because they are not part of the convenience kit.

Example 2: Non-sterile orthopedic device set

A collection of orthopedic devices comprises implants and reusable instruments that are all supplied non-sterile. Each of these devices is removed from its packaging to be placed into a sterilization tray[11] for cleaning and sterilization at some point prior to use, as intended by the labeler. Only a few of the implants in each set may be selected for implantation in a single procedure on a single patient. After the procedure, the sets are replenished with different implants, replacing those used during the procedure. The sterilization tray, the replacement implants, the implants that were in the sterilization tray prior to the procedure and not chosen for surgical use, and the reusable instruments, are all sterilized for potential use in subsequent surgical cases. This is not a convenience kit because the devices are not intended to remain packaged together without undergoing sterilization before being used by an end user. Therefore, each device must comply with all applicable UDI labeling, data submission, and direct mark requirements.[12]

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[10] Many first aid kits comprise co-packaged drug and device components and are therefore combination products (see 21 CFR 3.2(e)(2)). As stated earlier, this guidance document does not apply to combination products. Questions about combination products can be directed to combination@fda.hhs.gov.

[11] Although FDA has previously used the terms "kits" and "trays" interchangeably (see the UDI Rule at 78 FR 58800), the term "tray" may be confusing, as it may refer to an individual device (i.e., sterilization tray) separate from the other implants and instruments, or to the collection of implants, instruments and sterilization tray, or to a part of the packaging of a sterile medical device. In this guidance, "tray" is referring to the individual device.

[12] Direct marking requirements only apply to devices that are intended to be used more than once and intended to be reprocessed between uses (21 CFR 801.45). The Unique Device Identification: Direct Marking of Devices guidance (Direct Mark guidance) is available at

If these device sets were considered "convenience kits" for purposes of the UDI regulations, the single UDI required for the convenience kit would not differentiate between implants used on the patient and those remaining in the sterilization tray. This would be contrary to the objective of the unique device identification system, which is to provide adequate identification of medical devices through distribution and use.[13]

Example 3: Single use disposable medical procedure kit

A single use, disposable medical procedure kit, such as an anterior cruciate ligament (ACL) procedure kit, comprises sterile, single use instruments such as guide wires, drill tip guide pins, tunnel plugs, and a graft passer that are used for ACL reconstruction procedures. The kit comprises devices that are packaged and sealed in a single container, and the container is supplied sterile. The container is intended to remain sealed and the contents sterile until the contents are about to be used on a patient. All the devices are used for a single procedure on a single patient, or, if unused after a single procedure on a single patient, disposed of without being used because sterility has been compromised. This single use disposable medical procedure kit is a convenience kit because it is a device comprising individual devices packaged together for the convenience of the user and not intended to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user. Therefore, the label of each individual device within the container is not required to bear a UDI, provided that a UDI is available on the label affixed to the immediate container of the kit.

This example is distinguishable from Example 2, in which the devices are intended to be sterilized prior to use and intended to be reassembled and restocked between uses.

Example 4: Sterile kit containing both single-use and reusable medical devices packaged together

A suture kit contains single-use sutures and reusable stainless steel instruments, including forceps, needle holders, and scissors. The kit is supplied sterile, but after the initial procedure in which the single use device (suture) is consumed, the labeler intends that the instruments may be reused on different patients, which requires reprocessing before each subsequent use. This is a convenience kit because the individual devices within the device are packaged together for the convenience of the user and not intended to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user. Therefore, the label of each individual device within the container is

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https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM452262.pdf.

[13] See Footnote 7. Additionally, FDA included exceptions to the UDI requirements at 21 CFR 801.30 "to make the overall UDI system more efficient and to ensure that the burdens imposed by the UDI system are reasonably balanced with its benefits." UDI Rule at 78 FR 40749.

not required to bear a UDI, provided that a UDI is available on the label affixed to the immediate container of the kit.

In this example, some devices in the kit are intended by the labeler to be reprocessed and reused, and therefore those reusable devices are subject to direct mark requirements (21 CFR 801.45).[14]

Example 5: Different devices that are packaged together for the convenience of the user but the collection of devices is not itself a device

A labeler manufactures fluid-filled teething rings in a variety of shapes. The labeler packages one teething ring of each shape together as a fixed quantity to create an item for retail with a higher profit margin and/or to allow each end user to select and use a particular model of teething ring according to preference. This is not a convenience kit because the devices packaged together are not collectively a device.

C. Questions and Answers

1. To be considered a convenience kit for purposes of the UDI regulations, should all of the devices within a container be finished devices?

Yes. We interpret "medical devices" in the definition of "convenience kit" in 21 CFR 801.3 ("two or more different medical devices packaged together for the convenience of the user") to mean finished devices and not device components. Finished devices are defined by 21 CFR 801.3 as "any device or accessory to any device that is suitable for use or capable of functioning."

2. How much variation is allowed for different convenience kits to be identified by the same device identifier (DI)? If I substitute one device for another, will the kit need a new DI?

It is up to the labeler to determine when a change to a particular model or version of device results in a new model or version of the device. Under 21 CFR 830.50, whenever you make a change to a device that is required to bear a UDI on its label, and the change results in a new version or model, you must assign a new DI to the new version or model.

3. If all the devices in a container are not intended to be consumed in a single use, or used at the same time, can this be a convenience kit?

Yes. If devices packaged together otherwise meet the definition of a convenience kit for UDI compliance purposes, all of the contents of the kit need not be intended to be consumed in a single use or used at the same time in order to be considered a convenience kit. Example 1, above, is a convenience kit despite the fact that all the individual devices may not be

[14] See Footnote 11.

intended to be consumed in a single use. In that example, the devices within the first aid kit are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before initial use by an end user.

4. What production identifiers (PIs) must be included in the convenience kit UDI?

The convenience kit is itself a device. The UDI of the convenience kit must include any PIs on the convenience kit label that are required by 21 CFR 801.40(b), unless an exception[15] or alternative applies.

5. If my device meets the UDI labeling exception for a convenience kit under 21 CFR 801.30(a)(11), may I still place a UDI on individual devices or device labels in the kit?

Yes, 21 CFR 801.30(a)(11) is an available exception, not a requirement. You may place UDIs on devices or device labels within a convenience kit. If any individual devices with UDIs on the devices or device labels are included in a convenience kit, it may be useful to reference the DIs of the individual devices within the device identifier (DI) record for the convenience kit that is submitted to the Global Unique Device Identification Database (GUDID). Stakeholders using AccessGUDID,[16] the public portal for GUDID, often find it useful to know whether or not there will be a label to scan on devices in a kit and to have access to the additional information in the DI records of the kit.

6. Are there any special rules for creating a DI record in the GUDID for a convenience kit?

For technical recommendations on how to submit information to GUDID, including information relating to convenience kits, please visit FDA's website.[17]

[15] For example, pursuant to 21 CFR 801.30(d), the UDI of a class I device is not required to include a production identifier.
[16] *See* AccessGUDID available at: https://accessgudid.nlm.nih.gov/.
[17] Available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm.