Unique Device Identification: Convenience Kits

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800, email: ocod@fda.hhs.gov.

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

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

On September 24, 2013, FDA published a final rule establishing a unique device identification system, including unique device identifier (UDI) labeling and data submission requirements (78 FR 58786) (the UDI Rule). Generally, under 21 CFR 801.20, the label and device package of a device must bear a UDI; 21 CFR 801.30 provides exceptions to this requirement. Under 21 CFR 801.30(a)(11), devices packaged within the immediate container of a convenience kit are excepted from UDI labeling requirements, provided that the label of the convenience kit bears a UDI.

This draft guidance document is intended to outline the agency's proposed thinking that "convenience kit", as defined by 21 CFR 801.3, applies solely to two or more different medical devices packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user. This position would constitute a change in policy.

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.

Any terms defined within this draft guidance are limited in their application to this draft guidance document and the UDI regulations only and are not intended to be applied in any context beyond the UDI regulations and policies pertaining to the unique device identification system. This draft guidance is not intended to define the term "convenience kit" for other regulatory purposes.[1] Further, this guidance is in no way intended to suggest that compliance solely with the requirements of the UDI Rule eliminates the need to comply with any other applicable requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), its implementing regulations, or policies implemented thereunder.

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 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) and section 614 of the Food and Drug Administration Safety and Innovation Act (FDASIA) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add and amend section 519(f) (21 USC 360i(f)), which directs FDA to publish regulations establishing a unique device identification system for medical devices. On September 24, 2013, FDA published a final rule establishing a unique device identification system (the UDI Rule) (78 FR 58786). The UDI Rule requires labelers to comply with UDI labeling and data submission requirements, including 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.

Under 21 CFR 801.30(a)(11), individual devices packaged within 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. The term "convenience kit" is defined at 21 CFR 801.3 as "two or more different medical devices packaged together for the convenience of the user."

The preamble to the UDI Rule expressed our thinking at the time that medical procedure kits, including orthopedic procedure kits, are convenience kits. Some medical procedure sets consist of hundreds of implants and reusable instruments on numerous trays configured specifically to the requirements of the surgeon and individual surgical procedure. Only a few of the individual implants in each kit may be selected for implantation. After the procedure, the kits are replenished with different implants, replacing those used during the procedure.

[1] For example, the term "convenience kit" as used in this draft guidance document is not intended to be applied in interpreting the May 20, 1997, guidance entitled "Convenience Kits Interim Regulatory Guidance" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080216.htm). In addition, this draft guidance is not intended to apply to "medical convenience kit" as that term is used in 21 USC 360eee or 21 USC 353.

The trays, including the replacement implants, the implants not chosen for surgical use, and the reusable instruments, are sterilized for subsequent configuration and use. An individual implant may undergo this process repeatedly for months or years before implantation. Since the publication of the UDI Rule, we have determined that interpreting the term "convenience kit" to include implantable devices and instruments that are provided by the labeler in sets or trays as non-sterile and repeatedly reconfigured and sterilized (or cleaned and sterilized) prior to use would be inconsistent with the purpose of the exceptions at 21 CFR 801.30 and UDI Rule generally, for the reasons discussed below.

The overarching objective of the UDI Rule, 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 form of a UDI should, in conformity with 21 CFR 801.40, be available to identify a device in both easily readable plain-text and in a form that can be entered into an electronic patient record or other computer system via an automated process when the device is used by an end user. The term "end user" means the individual using the device on or on behalf of a patient (e.g., the patient, a caregiver, healthcare practitioner, or clinical laboratory technologist). FDA included exceptions to 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." (77 FR 40749).

Interpreting "convenience kit" in 21 CFR 801.3 as applying solely to devices packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user fulfills these purposes. Where the kit is not intended to be altered prior to use, for example by processing or replacing devices therein, the UDI on the label of the immediate container of the convenience kit serves to adequately identify the devices through distribution and use. The UDI on the label of the immediate container of the convenience kit follows the group of devices until end use; there is no need for additional UDIs on the devices inside the kit.

Conversely, excepting from UDI labeling and data submission requirements devices packaged together for the convenience of the user where they are not intended to remain packaged together and/or are intended to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user does not fulfill the purpose of the exceptions at 21 CFR 801.30 or the UDI Rule generally. The UDI on the label of the immediate container of the kit may not follow the group of devices until end use, and devices originally contained in the kit may be intended to be replaced. Such an exception would not adequately identify medical devices through distribution and use.

FDA believes that there are significant benefits to requiring UDIs on devices included in medical procedure kits, such as more rapid identification of adverse events and more rapid, more efficient resolution of device recalls involving these devices. Further, requiring UDIs on devices included in medical procedure kits will adequately identify these devices throughout distribution and use, furthering the main objective of the UDI Rule as required by

section 519(f) of the FD&C Act. FDA expects that this interpretation may also provide additional benefits such as inventory management and the detection of counterfeit devices.

The preamble to the UDI Rule noted that some comments to the proposed rule were concerned that applying UDI requirements to medical procedure kits would require changes in the way medical procedure kits are assembled and packaged, which could interfere with sterilization processes and the use of the medical procedure kit. FDA believes that the interpretation of "convenience kit" at 21 CFR 801.3, as proposed in this draft guidance, generally would not interfere with the sterilization or use of medical procedure kits. With respect to the direct marking requirement at 21 CFR 801.45, this requirement applies to devices that are intended to be used more than once and intended to be reprocessed before each use, which includes sterilization.[2] This requirement contemplates that direct marking of UDIs generally will not interfere with these devices' sterilization, and if it would interfere with the safety or effectiveness of the device, the exception at 21 CFR 801.45(d)(1) would apply. With respect to the requirement that the label and each device package bear a UDI, applying this to devices included in medical procedure kits generally would not necessitate changes to the way convenience kits are assembled and packaged to avoid interference with sterilization processes or the use of the kit. Even in cases that may require such changes, FDA believes that the benefits, as discussed above, would outweigh any burdens associated with this change in interpretation of "convenience kit" at 21 CFR 801.3.

In this draft guidance, FDA proposes to interpret the term "convenience kit" at 21 CFR 801.3 as applying solely to two or more different medical devices packaged together for the convenience of the user where they are intended to remain packaged together and the individual devices within the package not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user.

III. Convenience Kits

A. Definition

For the purposes of UDI compliance, we interpret the term "convenience kit" at 21 CFR 801.3 solely to apply to two or more different medical devices packaged together for the convenience of the user where they are intended to remain packaged together and not replaced, substituted, repackaged, sterilized, or otherwise processed or modified before the devices are used by an end user.

While the term "packaged together" is not defined by the UDI Rule, we interpret it to mean packed (i.e., wrapped or sealed) in a single container that is not intended to be unwrapped or unsealed before it is used by an end user. The end user is the individual using the device on or on behalf of a patient, e.g., the patient, a caregiver, healthcare practitioner, or clinical

[2] We also encourage affixing a UDI permanently on devices even when not required .

laboratory technologist. For example, in the case of implants, the implant would be used by an end user, likely a healthcare practitioner, at the point of implantation in a patient.

This draft guidance is intended to define the term "convenience kit" for purposes of compliance with UDI labeling and data submission requirements only.

B. Examples

Example 1: First aid kit – convenience kit

A first aid kit sold at retail in a sealed plastic case that contains medical devices including bandages, cold compresses, scissors, and an oral thermometer is a convenience kit for the purposes of UDI compliance because it 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 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.

Example 2: Non-sterile orthopedic device tray or set – not a convenience kit

An orthopedic device tray or set, sold or consigned, comprises non-sterile implants and reusable instruments. These devices are not intended to remain packaged together; rather, they are intended to be removed from their packaging before being placed in trays for a surgical procedure and sterilized prior to use, with the trays regularly reassembled and restocked for subsequent surgical procedures. This tray or set is not a convenience kit for the purposes of UDI compliance because the devices within the tray or set are intended to be removed from their original packaging and sterilized before use by an end user, i.e., prior to the point of implantation. Therefore, each device in the tray or set should comply with all applicable UDI labeling and data submission requirements. For example, each implant will need a UDI available for capture at point of implantation, and each instrument that is intended to be used more than once and intended to be reprocessed before each use will need to comply with the direct marking requirements of 21 CFR 801.45.

Example 3: ACL disposable kit – convenience kit

An anterior cruciate ligament (ACL) disposable kit comprises sterile, single use instruments such as guide wires, drill tip guide pins, tunnel plugs, and graft passer that are used for ACL reconstruction procedures and are packaged and sealed in a single container. The container is intended to remain sealed until the contents are about to be used on a patient. The contents are used for a single procedure and the remainder of the contents of the container is then disposed, whether or not all the devices were used, because sterility has been compromised. This is a convenience kit for the purposes of UDI compliance because the container

comprises two or more different devices packaged for the convenience of the user where they are intended to remain packaged together and the individual devices within the package not 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 immediate 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 .

Example 4: Reusable medical devices packaged together – not a convenience kit

Two different reusable surgical instruments are shipped in a single package. Per instructions for use, the package is opened and the instruments are sterilized before use on a patient. The package is not a convenience kit for the purposes of UDI compliance because the instruments are not intended to remain packaged together and each is intended to be sterilized before it is used by an end user Therefore, each instrument will need to comply with all applicable UDI labeling and data submission requirements. For example, each instrument that is intended to be used more than once and intended to be reprocessed before each use will need to comply with the direct marking requirements of 21 CFR 801.45.

C. Questions and Answers

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

Yes. We interpret "medical devices" in the definition of "convenience kit" at 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," in contrast to components, defined by 21 CFR 820.3(c) as "any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device." Components packaged together for assembly would not be packaged together for the convenience of the user. While a container of device components intended to be assembled into a single device may be considered a single device requiring a UDI (that is, a UDI is required on the label of the immediate container but not on the individual components), it does not fit the definition of convenience kit for UDI requirements.

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

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. A new version or model of a convenience kit results when the change to the convenience kit requires documenting this change in the device master record.

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 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 use by an end user.

4. If devices in a container are intended to be restocked by the labeler, would this still be a convenience kit?

No. In order to be a convenience kit as defined by 21 CFR 801.3, the immediate container cannot be intended to be opened and the individual devices replaced, substituted, repackaged, sterilized, or otherwise processed or modified before being used by an end user. In Example 1 above, the devices in the first aid kit are intended remain packaged together and not replaced; although the purchaser may replace devices consumed over time, such as bandages, this replacement is not intended by the labeler to occur prior to use by an end user.

5. 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 that are required by 21 CFR 801.40(b).

6. 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 exception, not a requirement. You may place UDIs on devices or device labels within a convenience kit. If individual devices with UDIs on the devices or device labels are included in a convenience kit, the device identifier (DI) record for the convenience kit submitted to the Global Unique Device Identification Database (GUDID) should include the DI for the kit itself and not the DIs for the individual devices in the kit. However, the individual device DIs may be included in the Device Description.

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

When entering information in the GUDID for a convenience kit, you should check the "Kit" box. Also, if the convenience kit is packaged individually, the base device count should be "1". A Unit of Use DI is not required for each device packaged within the immediate

container of the convenience kit. For more details, go to GUDID Data Elements Reference Table.

8. How do I describe the devices within the convenience kit in the GUDID?

We encourage you to submit information about the convenience kit itself, as well as information about the devices packaged within the convenience kit, in the "Device Description" field of the GUDID.