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Unique Device Identification: Convenience Kits Final Guidance

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Agenda

- Objectives
- Background
- Scope
- Definitions
- Convenience Kits Policy
- Stakeholder Considerations
- Examples

Objectives

- Become familiar with the content of the final guidance document issued on April 26, 2019
- Understand the FDA's interpretation of the definition of convenience kit for purposes of unique device identification as it applies to the exception at 21 CFR 801.30(a)(11)
- Understand the FDA's current thinking regarding medical procedure kits as convenience kits

Background

- The objective of the Unique Device Identification system is to adequately identify devices through distribution and use to facilitate:
 - Rapid identification of adverse events
 - More efficient management of recalls
 - Reduction in medical errors
 - Secure global distribution

Background

- Regulations require that the label and every device package of every medical device distributed in the United States bear a unique device identifier (UDI), unless an exception or alternative applies.
- Under 21 CFR 801.30(a)(11), individual devices packaged within the immediate container of a convenience kit are excepted from the UDI labeling requirements, if a UDI is on the label of the immediate container of the convenience kit.

Background

- The draft guidance on convenience kits published on January 4, 2016.
- In response to comments received on the draft guidance, the FDA narrowed the scope of the final guidance and made some clarifications.
- The final guidance on convenience kits published on April 26, 2019.

Scope

The Unique Device Identification Convenience Kits final guidance:

- Is not intended to be applied beyond the regulations and policies pertaining to the unique device identification system.
- Does not apply to in vitro diagnostic (IVD) devices that are subject to 21 CFR Part 809.
- Does not apply to combination products as defined in 21 CFR 3.2(e).

Convenience Kit

- **Convenience kit** is defined in the regulations as “two or more different medical devices packaged together for the convenience of the user” (21 CFR 801.3).
- The FDA interprets this to mean a convenience kit is 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.

Additional Definitions

- **Packaged together:** Packed (for example, 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:** Individual using the device on or on behalf of a patient, for example, the patient, a caregiver, a healthcare practitioner, or a medical technologist.
- **Medical procedure kit:** Typically consists of one or more medical devices, packaged together to facilitate a single surgical or medical procedure. A medical procedure kit *may* be a convenience kit.

Medical Procedure Kits

- The preamble of the UDI final rule expressed thinking that medical procedure kits containing two or more devices are “convenience kits.”
- This final guidance clarifies that under our interpretation of the term “convenience kit:”
 - **The FDA does not consider every medical procedure kit to be a convenience kit for purposes of UDI regulations.**
 - **The FDA does not consider every collection of two or more medical devices to be a convenience kit for purposes of the UDI regulations.**

If a device is a convenience kit...

- The exception at 21 CFR 801.30(a)(11) is not mandatory.
 - If a device is a convenience kit, as described in this final guidance, a labeler (typically, the manufacturer) may label each device within the kit with a UDI.
- In submitting convenience kit records to the Global Unique Device Identification Database (GUDID), it is helpful to note which devices in the kit, if any, will have a label with a UDI that can be scanned and which will not.

Stakeholder Considerations

- The FDA recognizes the interpretation of terms provided in this guidance may mean fewer medical procedure kits are “convenience kits” for purposes of the UDI regulations
- As for all devices, a labeler may request an alternative to a UDI requirement under 21 CFR 801.55, including the policies outlined in this guidance. In drafting a request for an alternative, please consider how the alternative will achieve the objectives of the Unique Device Identification system.

Example 1: Retail First Aid Kit

A first aid kit sold at retail that includes only devices packaged together:

- containing 2 or more different medical devices
- 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

Retail First Aid Kit

- A first aid kit sold at retail that includes only devices packaged together **is** a convenience kit.
 - It is a device
 - containing 2 or more different medical devices
 - 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
 - 21 CFR 801.30(a)(11) is applicable
 - If a UDI is on the label affixed to the immediate container of the convenience kit, then the label of each individual device within the container is not required to bear a UDI.

Retail First Aid Kit

- After purchase, the user may choose to replenish or modify the kit.
- A labeler may choose to market individual devices separately to the end user.
 - Label/packages of 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

Non-sterile orthopedic device set:

- Collection of non-sterile implants and reusable instruments
- Intended by labeler to be placed in sterilization tray for cleaning or sterilization before use
- Only a few of the implants are selected for use
- Unselected implants, used instruments, and new implants to replenish those used are cleaned and sterilized for potential use in future cases



Non-Sterile Orthopedic Device Set

A non-sterile orthopedic device set is **not** a convenience kit:

- Not intended to remain packaged together without undergoing sterilization prior to use.
- Each device must comply with applicable UDI labeling, data submission, and direct mark requirements.

Example 3: Single Use Disposable Medical Procedure Kit

A single use disposable medical procedure kit:

- Comprises different devices that are packaged and sealed in a single container, which is supplied sterile
- 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 during that procedure, disposed of

Single Use Disposable Medical Procedure Kit



A single use disposable medical procedure kit **is** a convenience kit:

- It is a device
 - containing 2 or more different medical devices
 - 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

- 21 CFR 801.30(a)(11) is applicable

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 and is supplied sterile:

- After the initial procedure in which the suture is consumed, the labeler intends that the instruments may be reused on different patients, which requires reprocessing before each subsequent use.

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



This kit **is** a convenience kit:

- 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.
- Items in the kit intended to be reprocessed and reused are subject to direct marking.

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 packages one teething ring of each (of a number) of models of varied shapes together as a fixed quantity to create an item for retail with a higher profit margin or to allow each end user to select and use a particular teething ring.

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



- This package is **not** a convenience kit.
 - Devices packaged together are not collectively a device.

Resources

- UDI Convenience Kit Final Guidance:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identification-convenience-kits>
- UDI Help Desk:
www.fda.gov/medical-devices/unique-device-identification-udi/fda-udi-help-desk

Questions?

UDI Help Desk: www.fda.gov/udi

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

Slide presentation, transcript, and webinar recording will be available at

www.fda.gov/training/cdrhlearn

under heading Unique Device Identification (UDI) System