Kits and the GUDID Entries That Describe Them

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To be a convenience kit...

Or not to be a convenience kit. That is the question...
Once upon a time, in a land before UDI
1997 Guidance: Purpose

• Intended to reduce regulatory burden on kit assemblers and FDA by providing enforcement discretion for kits comprising only cleared/approved/exempt devices

• Each constituent must be individually cleared/approved (or exempt) and packaged/labeled (Individual kit constituents should be “purchased in finished form, i.e., they should be packaged, labeled, etc., consistent with their legal marketing authorization”)
The UDI Rule was published in 2013
Convenience Kit: UDI Rule

• UDI rule defines “convenience kit” as “two or more different medical devices packaged together for the convenience of the user”

• Exception for devices packaged within the immediate container convenience kit, provided that the label of the convenience kit bears a UDI
Conflicts

Individual kit constituents should be packaged, labeled, etc., consistent with their legal marketing authorization (1997 Guidance)

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“two or more different medical devices packaged together for the convenience of the user” excepted from UDI label requirements (UDI Rule)
Is it a convenience kit?
The same term can mean different things in different regulatory contexts

If it looks like a convenience kit, if it smells like a convenience kit...
Collections of Devices

- Package Configuration
- Shipping Container
- Kit
  - UDI “Convenience Kit”
  - 1997 Guidance “Convenience Kit”

UDI
1997 Guidance

Slide 10
What is a Shipping Container?
Shipping Container

• A shipping container is not required to bear a UDI

• For UDI requirements, a shipping container is “a container used during the shipment or transportation of devices, and whose contents may vary from one shipment to another” (21 CFR 801.3)
A Shipping Container is...

- Container used to ship (no UDI)
- Contents may vary from shipment to shipment
- Materials used to protect shipment are not required to bear UDI
What is a Kit?
A Kit Is...

- Two or more different devices
- Packaged together
- To achieve at least one common intended use
Kit = Single Device

- A kit is itself a device
- A kit is required to bear a UDI on its label
What is a Convenience Kit?
Convenience Kits

• Nomenclature in the UDI final rule is unfortunate because it is opposite of 1997 Convenience Kit Interim Guidance use of the term

• Convenience kit definition in 21 CFR 801.3 is too broad/vague to result in adequate identification. For example, it would include shipping containers.
For UDI, A Convenience Kit is…

For UDI requirements, a convenience kit is “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”

- Draft Guidance “Unique Device Identification: Convenience Kits” (January 4, 2016)
A UDI Convenience Kit is…

Two or more different medical devices packaged together as a kit

Intended to remain packaged together until use by the end user, without replacement, substitution, sterilization, etc.
Package Configuration

- Package Configuration Requires UDI
- Shipping Container Does not require UDI
- Kit
  - UDI “Convenience Kit”
  - 1997 Guidance “Convenience Kit”
Why does it matter?

- UDI labeling requirements
- End user needs
- ONC and CMS requirements
- GUDID submission requirements
21 CFR 801.20

Requires the label of every medical device and every device package to bear a UDI unless an exception or alternative applies.
UDI Requirements: Existing labeling practices

- UDI was not intended to disrupt existing labeling practices, e.g. requiring labels on devices, that would not otherwise be individually labeled, solely for UDI compliance.

- Some collections of devices have been historically sold, ordered, used, and documented with one label on the package and no labels on the individual devices because
  - it is easiest/most efficient for the end user and/or
  - the devices within the collection are not sold any other way.
UDI Labeling Requirements: Exceptions

- UDI applies broadly to all medical devices, unless an exception or alternative applies.
- Some of the exceptions that apply to collections of medical devices:
  - 801.30(a)(3) (Bulk Package Exception) - Individual single-use devices, all of a single version or model, that are distributed together in a single device package, intended to be stored in that device package until removed for use, and which are not intended for individual commercial distribution are excepted from UDI label requirements when device package is UDI labeled.
  - 801.30(a)(11) (Convenience Kit Exception) - Devices within the immediate container of a convenience kit are excepted from UDI label requirements, if the convenience kit label bears a UDI.
  - 801.30(d) (Shipping Container Exception) – UDI rule does not require a UDI to be placed on any shipping container.
UDI Labeling Requirements: Bulk Package Exception

- Problems can arise when the original manufacturer, using the 21 CFR 801.30(a)(3) exception, does not label the individual devices with the UDI, but further down the supply chain, the individual devices are taken out of the package and separately distributed prior to end use.

- This issue will be further discussed at the UDI Low Unit of Measure Best Practices session at 11:45am today!
What is it if...

It isn’t a convenience kit?

It may be a kit. Is it

- Two or more different devices
- Packaged together
- To achieve at least one common intended use

It isn’t a convenience kit or a kit?

If it is neither a convenience kit nor a kit, then it is a package configuration (or a shipping container).
Confused?
Examples

Not a Convenience Kit

Convenience Kit
Example 1

A collection of finished and labeled devices that are not necessarily intended to be used together (3 stethoscopes, 6 saline bags, 10 packages of IV tubing, 2 boxes of gloves and 4 cartons of EKG electrodes) for delivery to a hospital unit per a single order.
Example 1 – Shipping Container

• Collection is not itself a medical device (a “kit”) because the collection is not based on an intended use, but includes a continually varying collection based on what a customer ordered today

• This is a shipping container
Shipping Container

- UDI rule provides shipping container exception
- No GUDID submission for shipping containers
Examples

Not a Convenience Kit

Convenience Kit
Example 2

A labeler manufactures two versions/models of blood glucose test kits. Model A is more popular than Model B. When sent to retailers and distributors, they are in an assorted case that always includes 5 of Model A and 3 of Model B.
Example 2 – Package Configuration

• Two or more different models/versions of devices packaged together for business reasons
• Though both blood glucose monitoring kits may have similar indications for use, combining Model A and Model B in a device package is not with the intent they are used together to achieve a common intended use
• This is a package configuration
User needs: Package Configuration

• UDI rule requires identification of every device package to facilitate adequate identification through distribution

• End users are beginning to build item masters based on DIs. They need package DIs for packages or units of purchase that are collections of devices.
• Kit flag = N

• Device description field should provide details on the package configuration that make it clear that it contains more than one model/version of device, including linkage to the DIs in the Model A and Model B GUDID records.

• We recognize that this approach is not optimal because the package configuration DI record will not appear as a higher level package for either Primary DI for Model A or Model B.
Examples

Not a Convenience Kit

Convenience Kit
Example 3

Sterile Procedure Pack:
Sterile, disposable laparotomy kit containing a Mayo stand drape, 4 standard drapes, a laparotomy drape, table cover, 2 hand towels, 2 gowns, and a paper suture bag in a single package
Example 3 - Convenience Kit

- 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 is a convenience kit for UDI purposes.
User Needs: Convenience Kit

• Kit designed to give end user exactly what is needed, no more/no less
• Devices are not individually packaged
• One number can be used to order, bill, and/or record use
• Adding packaging and/or labels where there were none disrupts care delivery and adds to cost for hospitals, both in time unwrapping/scanning and in disposal costs
Convenience Kit

- Kit flag = Y
- Device Packaged as Sterile = Y
- Especially because this is a UDI convenience kit and nothing is individually identified, the Device Description field is crucial
- Catalog Number should be entered
- No matter how many devices in the laparotomy kit, the device count = 1 (kit)
- Devices with device count = 1 have no Unit of Use DI
Examples

Not a Convenience Kit

Convenience Kit
Example 4

• Same as Example 3 but customizable
• Still a convenience kit for purposes of UDI
Customized Convenience Kit

• Up to the labeler to determine when a change to a device constitutes a new model/version of the device

• However, unless there is a relatively small number of potential customizations, which can be differentiated one from another by Device Description, creating a separate DI record for each customization can make it harder for end users to identify the device in AccessGUDID
  – Recommend accounting for this in PIs

• Device description should note the range of items that the kit typically contains, that the kit contents vary, and what that variation is dependent upon
Examples

Not a Convenience Kit

Convenience Kit
Example 5

- Several implant components (inflatable band, access port and tubing) and multiple sterile accessories (calibration assembly, end plug, closure tool, needles) together in one package under one label. It is all used or disposed of in a single procedure.
Example 5 – Convenience Kit

• Nothing in the box is replaced, substituted, repackaged, sterilized, processed or modified before the devices are used by an end user

• Fits proposed thinking on UDI convenience kit in the draft guidance
Existing Workflows

Existing workflows in hospitals (e.g., when they unpack different parts of the kit and record information from the label into medical records) have been based on how device has always been packaged and labeled before UDI.
User Needs

Does it matter to end users or patients if UDI of the kit reflects PIs of the kit and not of the individual devices?
User Needs Con’t

• With one UDI, will there be confusion on what to record in the EHR as the “implant” UDI?
• For kits with a multi-component implant that can be separately revised, how do you reflect a partial revision in the EHR?
• UDI adds possibilities. Could different identification better serve user needs?
  – Will multiple UDIs for this kit create more or less confusion on what to record in the EHR? More or fewer errors in device documentation?
Implant Procedure Kit

Kit flag = Y

As with other kits, Device Description is very important
- What the kit includes
- What the kit does not include
- What is the common intended use
- Are the devices in the kit also available separately
- Are the devices in the kit separately identified by UDI
Examples

Not a Convenience Kit

Convenience Kit
Example 6

- Non-sterile orthopaedic implants and instruments in a sterilization tray
- To ensure adequate options, many more implants are supplied in the tray than expected to be used in a single surgical procedure.
- Implants are selected and removed as needed. They are later replaced and the tray is sent for cleaning and sterilization between uses.
User needs for implant devices

2015 Edition §170.315(a)(14) Implantable Device List
UDI in Common Clinical Data Set
January 2018 – Create and Transmit Patient Implantable Device list
User needs for implant devices

• One UDI for the entire collection of devices in the tray cannot sufficiently differentiate/identify which devices were implanted during a procedure and which remained in the tray.

• Longstanding practice in medicine to record information about implanted devices in patient medical records but now those records can be made less ambiguous by use of UDI as the standard method of identifying the device.

• Implant UDIs are being recorded into EHRs by growing number of stakeholders, especially due to ONC rule and CMS rule.
Non sterile Implant Trays

- One DI record for each device in the tray
- One DI record for the sterilization tray itself
- Fields including Device Description and Brand Name and Catalog Number are important to make linkages between these devices
Examples

Not a Convenience Kit

Convenience Kit
Label Your Kits and Submit Your Data!

Despite your challenges, please do label your kits and enter your data in GUDID.

(1) hospitals and other end users trying to implement UDI rely on UDI and data availability of data

(2) until end users test drive the UDI kit labels and data to help us identify what does/does not work, as not everything is black or white
Questions?

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

Subject: Kits
Question 1

A kit, not a convenience kit for UDI purposes, is assembled prior to the class I or unclassified compliance date and includes class I or unclassified device constituents that do not yet bear UDIs. What do we do?