April 4, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-D-4048: Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

To Whom It May Concern:

The Advanced Medical Technology Association (“AdvaMed”) appreciates the opportunity to provide comment on the Food and Drug Administration’s (“FDA” or “Agency”) Draft Guidance for Industry and Food and Drug Administration Staff: Unique Device Identification: Convenience Kits (“Draft Guidance”). AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators and companies.

We appreciate FDA providing clarity concerning the treatment of convenience kits under the unique device identification (“UDI”) rules. We also commend FDA for providing examples and questions and answers in the Draft Guidance that help refine the Agency’s thinking with respect to convenience kits.

As an initial matter, we question the need for the Global Unique Device Identification Database (“GUDID”) to contain the “kits” data element. The benefit of this information is unclear, and the requirement continues to cause significant confusion. Should FDA maintain the “kits” data element, we recommend revising the GUDID so that the selection of this item does not automatically trigger the entry of a new device identifier (“DI”). Furthermore, we recommend FDA allow for the “kits” data element to be editable after the grace period. We are particularly concerned that GUDID entries may require changes based on the final version of this Draft Guidance. Lastly, FDA should align the terminology used in the Draft Guidance and GUDID Data Elements Reference Table to ensure they are applied in a consistent and accurate manner, including terms such as “convenience kit,” “kit,” and “medical procedure kit.”

FDA should also provide guidance concerning the treatment of a parent device packaged with its accessories. We recommend FDA clarify that:

- An accessory packaged and sold with a parent device (e.g., as a device “system”) does not require its own UDI; instead, the system would bear its own UDI.

- An accessory that is individually labeled, packaged, and intended to be sold separately from the parent device, including a replacement accessory, requires its own UDI.

Further guidance is also required as to whether these parent/accessories examples are “convenience kits” for GUDID data submission purposes, or whether device systems in general are afforded their own exception.²

Below we discuss several additional issues for the Agency’s consideration. Our specific comments in response to the text of the Draft Guidance are provided in the attached document.

I. Preservation of Existing IVD Policy

FDA should clarify that the Draft Guidance does not alter existing UDI policies for in vitro diagnostic (“IVD”) test kits. In this regard, the preamble to the UDI final rule states:

“Section 801.30(a)(11) now provides that the label of devices packaged within the immediate container of a convenience kit do not have to bear a UDI as long as the label of the convenience kit bears a UDI. This change will make clear that labelers do not have to change the way they label convenience kits, including in vitro diagnostics kits, except for including a UDI on the kit label.” 78 Fed. Reg. 58786, 58792 (Sep. 24, 2013).

FDA’s current IVD policies have allowed industry to achieve UDI compliance and implement a strategy based on the kit status of IVD test kits. Any change in this position will negatively impact the IVD industry, including labels of hundreds of products, and require significant industry and FDA resources to modify hundreds of GUDID entries. As a result, we ask that FDA clarify that the Draft Guidance does not impact UDI policies for IVD test kits.

II. Definitions

We believe the Draft Guidance should include a broader list of definitions than what is currently provided. In this regard, there are several terms that seem to be used in an inconsistent manner in the Draft Guidance and FDA’s GUDID data element chart. The

² We also recommend FDA clarify that “components” are not medical devices and do not require a UDI, even if sold separately as a replacement.
following terms should be better defined to ensure a common understanding of their distinctions:

1. Medical procedure kit (as used in the Draft Guidance and as distinguished from convenience kit);

2. Kit (as used in the GUDID data element table, which includes convenience kits, combination products, medical procedure kits, and IVD kits); and

3. Package configuration.

III. **Examples:**

We appreciate the examples provided in the Draft Guidance and find them helpful to better understand the Agency’s policy. We recommend that FDA present them in table format and provide each with a discussion of the following items: (1) Scenario; (2) description of device (e.g., convenience kit, package configuration, IVD, etc.); (3) UDI label requirement; and (4) GUDID data requirements.

In addition, we recommend adding the following example to the Draft Guidance:

*Medical devices packaged together for distribution purposes – not a convenience kit.* Two or more medical devices packaged together solely for distribution/ordering purposes would not be considered a convenience kit.

IV. **Questions and Answers:**

Similar to the examples, the questions and answers provided in the Draft Guidance are helpful. Below we offer several additional questions and answers that we believe will help further refine the Agency’s policy.

1. **Determining whether a product is a “convenience kit”**

   **Q1:** If a medical device package contains multiple devices, accessories, or items, some of which are not a medical device, is the device a kit?

   **A1:** Yes. If two or more finished devices are packaged together to facilitate a surgical or medical procedure, it is a convenience kit. A finished device means any device or accessory to any device that is suitable for use or capable of functioning.

   **Q2:** If a device package contains multiple single device packages with the same version/model number, is it a convenience kit?
A2: No. This would be considered a package configuration and should be entered as a package configuration on the DI record of the single device package. The unit of use would be a quantity of 1. The “kit” data element in the GUDID should not be checked.

Q3: If a device package contains medical electrical equipment, components and additional device packages that together make up a system, is the device package a convenience kit?

Example: An ultrasound system is sold with detachable probes that are not packaged together. The ultrasound base unit has a UDI to cover the CPU, monitor, keyboard and mouse, while the detachable probes have unique UDIs because they are interchangeable and also sold separately.

A3: No. For the device (ultrasound machine) and other non-medical device items (e.g., CPU, monitor, keyboard, mouse, etc.) packaged together in a single device package, a UDI would be required on the single device package. In the GUDID this single device package would not be checked as a “kit.” The additional device packages (e.g., detachable probes), which contain their own UDI would be separately entered into the GUDID and also would not be checked as a “kit.”

Q4: Are IVDs comprised of separate reagents, solutions and/or other individual components considered a convenience kit?

A4: Yes. For purposes of 21 C.F.R. 801.30(a)(11), IVDs comprised of separate reagents, solutions and/or other individual components are considered convenience kits. Furthermore, these device packages should be checked as a “kit” in the GUDID.

2. Labeling

Q1: Does a combination product which properly bears a National Drug Code (NDC) on its label require a UDI?

A1: No. A combination product, as defined by 21 C.F.R. § 3.2(e), that properly bears an NDC number is exempt from the UDI requirements per 21 C.F.R. § 801.30(b)(1). A combination product that does not bear (or is not subject to) an NDC does require a UDI.

Supporting regulatory rationale:
In general, combination products are exempt from UDI requirements: 21 C.F.R. § 801.30 (a)(11) states that the label of a device packaged within the immediate container of a combination product is not required to bear a UDI, provided that the label of the combination product bears a UDI. 21 C.F.R. § 801.30(b)(1) states that combination products are not subject to the UDI requirements of 801.20. And 21
C.F.R. § 801.30(b)(2) states that a “single entity combination product” (as defined by 3.2(e)(1)) is not subject to the UDI requirements of 801.20.

However, 21 C.F.R. § 801.30(b)(3) makes this exemption ambiguous because it states that the device constituent of a “co packaged” combination product (as described by 3.2(e)(2-4) must bear a UDI on its label, unless it meets the provisions of 801.30 (a)(11) and includes the UDI on the combination product itself (rather than the device constituent). The NDC number and respective serialization requirements provide sufficient support to permit tracking and identification as intended by the UDI regulations and eliminates redundant requirements. As a result, combination products are not required to bear a UDI.

**Q2:** For customizable configurations of multiple, individually packaged medical devices (each of which are labeled with their own UDI) does the overall customized package require a UDI?

**A2:** No. There is no requirement to have a UDI on the larger, customized package because each individually packaged medical device is already labeled with a UDI. Labeling the larger, customized package with a UDI would be considered voluntary pursuant to 21 C.F.R. § 801.35. Similarly, the GUDID data entry for the larger, customized package would be considered voluntary under 21 C.F.R. § 801.35. However, a GUDID data entry for each individually packaged medical device would be required under 21 C.F.R. § 830.

* * *

AdvaMed would like to thank the FDA for its consideration of these comments. Please do not hesitate to contact me at 202-434-7224 or zrothstein@advamed.org if you have any questions.

Respectfully submitted,

/s/

Zachary A. Rothstein, J.D.
Associate Vice President
Technology and Regulatory Affairs

Attachment
### AdvaMed Comments

**Date:** April 4, 2016  
**Document Title:** Unique Device Identification: Convenience Kits; Draft Guidance for Industry and Food and Drug Administration Staff  
**Submitters Name:** Zachary A. Rothstein, JD  
**Company:** Advanced Medical Technology Association (AdvaMed)

<table>
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<tr>
<td>2</td>
<td>71-73</td>
<td>Revise to: “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.”</td>
<td>N/A</td>
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<td>3</td>
<td>80</td>
<td>We recommend clarifying that the term “instruments” applies to surgical instruments used with implantable devices (e.g., screw drivers).</td>
<td>This revision helps clarify the Draft Guidance.</td>
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<td>4</td>
<td>128-131</td>
<td>Delete this sentence and its associated footnote: “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. (fn: We also encourage affixing a UDI permanently on devices even when not required.).”</td>
<td>We are concerned that FDA is creating a new policy in Footnote two, which encourages affixing a UDI permanently on devices even when not required. This reference is confusing and outside the scope of the Draft Guidance. Therefore, the sentence and footnote should be deleted.</td>
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<td>5</td>
<td>135</td>
<td>“… applying this to devices included in medical procedure convenience kits generally would . . .”</td>
<td>Use of the term “medical procedure kits” is unclear.</td>
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<td>6</td>
<td>179-192</td>
<td>Add at the end of the example: “Industry and FDA have been working on solutions that meet the spirit of the UDI regulation and may include use of exceptions (e.g., for size or other constraints).”</td>
<td>This statement adds clarity to the phrase, “UDI available for capture at point of implantation.”</td>
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<td>7</td>
<td>188-192</td>
<td>Revise to: “Therefore, for purposes of this example, the each device 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 . . . . Therefore, each device in the tray or set, or the tray itself.”</td>
<td>This revision clarifies that there may be scenarios in which the manufacturer appropriately labels their devices in different ways.</td>
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<td>8</td>
<td>189</td>
<td>Clarify the “data requirements” referred to in this and other examples.</td>
<td>This example, in addition to the others provided in the Draft Guidance, would benefit from additional clarity concerning GUDID entries. For example, Example 1 should state that the device should be entered into the GUDID as one DI record, and the “kit” data element should be selected. In contrast, for examples that are not kits, it should be stated that each device should be separately entered into the GUDID and the “kit” data element should not be selected.</td>
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<td>9</td>
<td>207</td>
<td>We recommend clarifying that “immediate container” may include a double barrier sterile tray or other container delivered to the point of use in a sealed, labeled box.</td>
<td>We believe this change provides needed clarity.</td>
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<td>10</td>
<td>210</td>
<td>Additional clarity is needed concerning GUDID data submissions for this scenario. While we agree that different reusable surgical instruments shipped in a single package are not a convenience kit, the GUDID accepts only one direct mark DI per record. It is unclear in this situation which DI should be entered in the database if a DI record is also submitted for the single package, in addition to submitting a DI record for each device within the single package. (We note that the reusable products are not commercialized separately, they are only provided to end users in a single package). Furthermore, the Draft Guidance should clarify that if a UDI compliant label is applied to the single package voluntarily, per 21 C.F.R. § 801.35, the DI is not required to be submitted to the GUDID.</td>
<td>This example raises several GUDID submission questions that require further explanation.</td>
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<td>11</td>
<td>232-233</td>
<td>Delete: “Components packaged together for assembly would not be packaged together for the convenience of the user.”</td>
<td>While we agree with FDA’s answer to Question C.1, this particular sentence is inaccurate in light of standard industry practices. There are times when multiple components are packaged together specifically for the convenience of the user (e.g., trays and dental cements and/or dental impression materials).</td>
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<td>12</td>
<td>245-246</td>
<td>Delete: “A new version or model of a convenience kit”</td>
<td>The sentence on lines 243-245 address the UDI requirements; the</td>
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<td>13</td>
<td>259</td>
<td>We recommend providing additional clarity concerning the term “restocked.”</td>
<td>This term is used in many contexts in the medical device industry. Providing a more clear definition of what this example is explaining would be helpful.</td>
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<td>14</td>
<td>272</td>
<td>Revise to: “For purposes of this example, the convenience kit is itself a device. If the convenience kit is a class I device, the manufacturer may take advantage of the exception provided in 21 C.F.R. § 801.30(d). Furthermore, if applicable, the UDI of the convenience kit must include any production identifiers that are required by 21 C.F.R § 801.40(b).”</td>
<td>Production identifiers are not required for Class I devices.</td>
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<td>15</td>
<td>279-284</td>
<td>Clarify that placing a UDI on individual devices or device labels in a convenience kit with a UDI is voluntary, consistent with 21 C.F.R. § 801.35. Furthermore, FDA should clarify whether the labeler is required to enter a DI record for each device and not check the “kit” data element in the GUDID if it chooses to not label under 21 C.F.R. § 801(a)(11).</td>
<td>While we support use of UDIs on individual devices, we are concerned that, as drafted, this response creates an expectation that components of a convenience kit should have their own individual UDI.</td>
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| 16 | General | We recommend adding the following statement to the Draft Guidance or otherwise including this language in the Federal Register Notice announcing release of the final guidance: “This interpretation of convenience kits does not alter the application of UDI to in vitro diagnostic test kits. A UDI is not required on the label of individual items contained within an IVD test kit, provided that the label of the IVD test kit bears a UDI. When entering information in the GUDID for an IVD test kit, you should check the ‘Kit’ box.” | In announcing this change in policy relating to the definition of convenience kit for purposes of UDI, it is important that the Agency confirm it is not changing its position on the application of UDI to IVD test kits because FDA relied on the term convenience kit in articulating the application of UDI to IVD test kits. In November 7, 2012 comments to docket FDA-2011-N-0090, available at http://www.regulations.gov/#/documentDetail;D=FDA-2011-N-0090-0157, AdvaMed, on pages 14-16, identified the need to clarify the applicability of UDI to IVD test kits. Specifically, AdvaMed recommended FDA add to the final rule the following text specific to IVDs: “[a] UDI is not required on the label of individual components contained within an IVD test kit if such components are
### General

In the GUDID Data Elements Reference Table, we recommend FDA replace “New DI Trigger” field with “No” and “Edit Rules After Grace Period” to “Edit” for the “Kit” field. As industry continues to understand and apply FDA’s definition of “convenience kit” as it applies to UDI implementation, these changes will allow manufacturers to make corrections to published DI records without contacting the UDI Help Desk.

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<td>In the GUDID Data Elements Reference Table, we recommend FDA replace “New DI Trigger” field with “No” and “Edit Rules After Grace Period” to “Edit” for the “Kit” field.</td>
<td>As industry continues to understand and apply FDA’s definition of “convenience kit” as it applies to UDI implementation, these changes will allow manufacturers to make corrections to published DI records without contacting the UDI Help Desk.</td>
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FDA addressed this comment in the preamble to the final rule with the following: “Section 801.30(a)(11) now provides that the label of devices packaged within the immediate container of a convenience kit do not have to bear a UDI as long as the label of the convenience kit bears a UDI. This change will make clear that labelers do not have to change the way they label convenience kits, including in vitro diagnostics kits, except for including a UDI on the kit label” (emphasis added). Additionally, FDA’s GUDID Data Elements Reference Table instructs individuals to check the “Kit” box when entering information in the GUDID for an IVD test kit. By linking the FDA response on IVD test kits to convenience kits, it is imperative that any change in convenience kit policy clarify that it does not change UDI policies for IVD test kits. Based on FDA’s response to the industry comment in the preamble and the instructions pertaining to GUDID entry, industry has achieved compliance and implemented a strategy based on the kit status of IVD test kits. Any change in this position will negatively impact the IVD industry, including labels of hundreds of products and industry and FDA resources to modify hundreds of GUDID entries.