DuVal CLIENT ALERT

Passing on Tribal Knowledge of FDA Law

DuVal Client Alert – AUGUST 2015

NEXT UDI DEADLINE: Thursday, September 24, 2015

Are you ready for another UDI deadline?

Part of our ongoing series on UDI

NEWS FLASH: GUDID Submission Compliance Date pushed out to October 24, 2015 for some devices[1]

[1] On August 18, 2015, FDA announced its intention to exercise enforcement discretion to extend the September 24, 2015 GUDID submission compliance date for implantable, life-supporting and life-sustaining medical devices to October 24, 2015 due to security issues with GUDID. *See* http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM458634.pdf.

EXECUTIVE SUMMARY

Are you ready for September 24, 2015? In just over a month, several categories of Class I and II devices will reach their compliance due date for labeling requirements under the Unique Device Identification ("UDI") regulations. The month following that, companies should be ready to submit device information on implantable, life-supporting and life-sustaining devices to the Global Unique Device Identification Database ("GUDID). These compliance dates are the second phase of UDI implementation which started in 2014 with Class III devices. The UDI system implementation will continue until September 24, 2020, at which time all devices should be compliant with the UDI regulations.

Failure to comply with the UDI rule is not an option for almost all medical device companies. The UDI regulations contain many requirements, exceptions and nuances, so a proactive approach of understanding what you need to know about UDI will help you achieve compliance when you need it.

We can help you achieve UDI compliance. Our associate, Amy Fowler, is an expert on UDI and has co-authored a BSI white paper on UDI which you can get by clicking here: "What You Need to Know About the FDA's UDI System Final Rule." Assisting her is another associate, Beth Luoma. This Client Alert highlights the basics of the UDI statute, regulations and guidance. When the due date for your device comes, will you be ready? If you have already started implementing UDI, are you missing anything else? Read this Client Alert to find out.

Brief Overview of UDI

The final rule ("UDI Final Rule") establishing a unique device identification system was published on September 24, 2013.[2] This Rule was not a fast thing coming. Both the Food and Drug Administration Amendments Act of 2007 ("FDAAA") and the Food and Drug Administration Safety and Innovation Act of ("FDASIA") 2012 required FDA to establish such a system to identify medical devices through their distribution and uses. Although the UDI Final Rule finally arrived in late 2013, the envisioned tracking system phases in the compliance dates over the course of

[2] Unique Device Identification System, 78 Fed. Reg. 58785 (Sept. 24, 2013).

seven years so that industry can prepare to implement the new requirements. For more on UDI compliance due dates, see the section, "***September 24th***."

The UDI system is comprised of two main requirements: a labeling requirement and a data submission requirement. The labeling requirement requires that every device label and every device package must contain a UDI unless an exception applies. The data submission requirement requires medical device labelers to submit certain information about a device through the FDA's Global Unique Device Identification Database ("GUDID"). The purpose of the UDI system is to identify medical devices through their distribution and use, which, among other things, enables easy access to important information about devices, improves the accuracy of device-related adverse event reports, and enhances the effectiveness and efficiency of medical device recalls.[3]

The primary requirement through which these objectives are achieved is through the UDI itself. The UDI of a device UDI is a string of numeric or alphanumeric characters that consists of two parts: a device identifier ("DI") and a product identifier ("PI").

The DI is a fixed portion of the character string which identifies the company (i.e., labeler) name and an item number denoting a specific version or model of the device. The PI is a variable portion of the character string which identifies the production information for that specific device, such as the lot or batch number, the serial number, and dates of expiration or manufacture.

Once the UDI is established for a device, various data elements about the device must be submitted by the labeler to GUDID. The GUDID database is public, and is expected to be a complete repository of existing medical devices by 2020 (the final UDI compliance due date).

Your First Steps for Achieving Compliance with UDI

It is essential to understand the UDI Final Rule and your requirements for compliance. Failure to comply by a UDI due date renders a device misbranded under the Federal Food Drug & Cosmetic Act ("FDCA"), resulting in potential

[3] Food and Drug Administration, Unique Device Identification System: Small Entity Compliance Guide - Guidance for Industry and Food and Drug Administration Staff, issued August 13, 2014.

enforcement actions which may include seizure, injunction, and civil and criminal penalties.

Almost all medical devices will be subject to the UDI system. The UDI regulations contain many requirements, exceptions and nuances. The purpose of this Client Alert is to get you acquainted with a few parts of the rule as you chart your course for achieving UDI compliance.

Assess Whether You Are Responsible for Maintaining UDI Compliance with Your Product

The first step you should take is to determine whether you are responsible for assuring that your product complies with UDI. This requires you to determine that (1) your product is a medical device, and (2) you are the labeler of that medical device.

- ✓ ***Do you have a "medical device?"***

You may have already answered this with an unequivocal "yes." Nevertheless, for some it is good practice to understand if your product is a medical device. If your product is labeled, promoted or used in a manner that meets the definition of a "device" under FDCA, your product may need to comply with the UDI requirements. Section 201(h) of FDCA provides that a **device** is:

> "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> > (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> > (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> > (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of

> man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."[4]

Combination products can contain a medical device, and the UDI Final Rule does not categorically exempt combination products (i.e., combination products must comply with UDI, unless an exception applies). The UDI Final Rule does provide some requirement exceptions to certain combination products, but generally the combination product must bear a UDI.[5]

- ✓ ***Are you the "labeler?"***

The UDI Final Rule provides that labelers are responsible for creating and assigning a UDI, correctly labeling their devices with UDI, and submitting data about their devices to GUDID. Since the burden of noncompliance rests with the labeler, you must determine whether you are a labeler for the purposes of UDI. The UDI Final Rule defines "labeler" as follows:

> …any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and, any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.[6]

In many situations, the device manufacturer or the specification developer will be the labeler. However, there may be situations where one company is the labeler of another company's device. FDA provides an example where "if you remanufacture and place a new label on a device, you are a labeler for purposes of the UDI Rule."[7] If you are the labeler, you are required to comply with the UDI Final Rule.

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[4] Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).
[5] 21 CFR § 801.30(a)(11).
[6] 21 CFR § 801.3.
[7] Food and Drug Administration, Unique Device Identification System: Small Entity Compliance Guide - Guidance for Industry and Food and Drug Administration Staff, issued August 13, 2014.

You may also be in situations where your company and another company jointly brought a product to market, and you will need to agree upon who will be designated the labeler. As described above, the DI indicates the name of the labeler; only one name can be listed. Taking on responsibility for complying with UDI is not a simple task, so proactive action and thought are need for coming to an agreement.

Determine If Your Device Is Not Required to Bear a UDI

Generally, a UDI is required to appear on the label of every medical device and every device package. There are some instances, however, where the UDI Final Rule provides exceptions to the UDI system. These exceptions mainly affect the following kinds of devices:

- **Devices in your existing inventory.** This applies to finished devices manufactured and labeled prior to its FDA assigned UDI compliance date, and expires three years after that assigned UDI.
- **Class I devices that are exempt from the good manufacturing practice requirements**.
- **Devices not intended for clinical use.** These devices are those which are used solely for research, teaching, or chemical analysis.
- **Custom devices.**
- **Investigational devices**.
- **Veterinary medical devices**.
- **Devices intended only for export**.
- **Devices held by the Strategic National Stockpile which have been granted an exception**.
- **Devices conforming to an FDA-recognized performance standard that provides an exception**.

Labelers may also submit a request for an exception under 21 CFR 801.55 if the labeler believes that the UDI labeling requirements are not technologically feasible. Absent being an excepted device or being granted an exception, all devices must comply with the UDI system and labeling requirements.

Aside from exceptions to UDI, the UDI Final Rule also provides exceptions to the labeling requirement for devices which otherwise are not exempt from UDI. See the following section, "***Know the UDI Labeling Requirements and the Exceptions to the Requirements***."

Know the UDI Labeling Requirements and the Exceptions to the Requirements

✓ *Direct Marking Requirements*

The UDI Final Rule requires that devices intended to be reprocessed and reused must bear a permanent marking of the UDI. Such devices are "intended to be used more than once" and "intended to be reprocessed before each use."[8] Although the UDI Final Rule does not define "intended to be used more than once" or "reprocessed," subsequent FDA guidance provides FDA's interpretation of these terms. FDA interprets "intended to be used more than once" as "intended for repeated uses on or by different patients."[9] FDA also interprets "intended to be reprocessed" to mean a device "intended to be cleaned and either sterile or disinfected before each use."[10] Therefore any device intended for use by the same patient, or which is intended to be merely cleaned between uses by different patients, is not subject to the direct marking requirements.

Nevertheless, there are exceptions for devices which would otherwise be subject to the direct marking requirement. These exceptions affect the following types of devices:

- Devices in which direct marking hinders its safety or effectiveness;
- Devices where it is not technologically feasible to directly mark;
- Single-use devices subject to further processing and manufacturing for the purpose of an additional single use; and
- Devices that have already been directly marked.[11]

[8] 21 CFR § 801.45(a).
[9] Food and Drug Administration, Unique Device Identification: Direct Marking of Devices- Guidance for Industry and Food and Drug Administration Staff, issued June 26, 2015.
[10] Id.
[11] 21 CFR § 801.45(d).

✓ ***Packaging Requirements***

The UDI Final Rule requires that each level of the packaging has its own UDI, unless the rule provides an exception.[12] A device package means "a fixed quantity of a particular version or model of a device."[13] Essentially this means that all of the various levels of device packaging (or measures of units) must be labeled with its own UDI. For instance, if a device is sold either as an individual device package or as a box containing five device packages, a different UDI would be needed for the individual device package and for the box of multiple units.

✓ ***Date format requirements***

The UDI Final Rule also requires a standard format for dates on medical device labels. This is a requirement regardless of whether a UDI exception applies to a device or not. If your label includes a date intended to be brought to the attention of the user of the device, that date is required to contain only numeric characters and be displayed as YYYY – MM - DD (e.g., January 2, 2014 must be presented as 2014-01-02).[14]

September 24th

The UDI compliance due dates for device labels and device packages are being phased in over a seven-year period based on the risk factor of the device. Failure to comply will render your device misbranded upon its compliance date.

Device	General UDI Due Date	Direct Marking Due Date
Class III devices (including life-supporting or life-sustaining) Devices licensed under the Public Health Service Act	September 24, 2014.	Life-supporting or life-sustaining: September 24, 2015 All other Class III devices: September 24, 2016

[12] 21 CFR § 801.20(b).
[13] 21 CFR § 801.3.
[14] 21 CFR § 801.18(a).

Device	General UDI Due Date	Direct Marking Due Date
All other implantable devices (Class II, Class I & unclassified)	GUDID Submission Requirements: October 24, 2015* All other General UDI Requirements: September 24, 2015	N/A
Life-supporting or life-sustaining devices (Class II, Class I & unclassified)	GUDID Submission Requirements: October 24, 2015* All other General UDI Requirements: September 24, 2015	September 24, 2015
All other Class II devices	September 24, 2016	September 24, 2018
All other Class I devices or unclassified devices	September 24, 2018	September 24, 2020

*As noted in the News Flash in the beginning of this Client Alert, FDA has announced its intention to exercise enforcement discretion to extend the September 24, 2015 GUDID submission compliance date for implantable, life-supporting and life-sustaining devices to October 24, 2015. This extension was due to security issues in GUDID which required FDA to take the GUDID system offline for maintenance.

Know Your UDI Resources

✓ *Final Rule*

Various parts of title 21 of the CFR have been amended to implement the UDI Final Rule. You can read the UDI Final Rule on its own and in its entirety, along with other supplementary information, on the Federal Register.[15]

✓ *FDA* Guidance *Documents*

The main set of resources is the FDA guidance documents related to UDI. These provide FDA's current thinking about the UDI rules, and provide clarifications to

[15] Unique Device Identification System, 78 Fed. Reg. 58785 (Sept. 24, 2013).

requirements and exceptions to the rule. Four UDI guidance documents have been issued at the time of this Client Alert.

The first issued guidance on UDI was the Global Unique Device Identification Database (GUDID) ("GUDID Guidance").[16] This guidance covers the Global Unique Identification Database ("GUDID) and provides information about the submission process, such as the user accounts, technical descriptions of submission options, package level requirements, and data attributes from example labeling.

The second issued guidance was the Unique Device Identification System: Small Entity Compliance Guide ("Small Entity Guidance").[17] The Small Entity Guidance provides an overview of the UDI Final Rule and what is required by the rule. Although this guidance is titled, "Small Entity," it is generally applicable for most labelers (small and large companies).

Next, FDA issued the Unique Device Identifier System: Frequently Asked Questions, Vol. 1 ("UDI FAQ Guidance").[18] In the form of frequently asked questions, FDA summarizes main features of the UDI Final Rule, such as UDI basics, UDI Placement, GUDID, direct marking, and exceptions and alternatives to the rule. (Please note that FDA has not issued a FAQs Vol. 2 as of the date of this Client Alert.)

Most recently, FDA issued the Unique Device Identification: Direct Marking of Devices ("Direct Marking Guidance").[19] As the title would suggest, this guidance addresses direct marking. This guidance also covers the finer details, such as when direct marking may require a premarket approval supplement or other marking application, and FDA's interpretation of terms relating to devices requiring UDI direct marking.

[16] Food and Drug Administration, Global Unique Device Identification Database (GUDID) - Guidance for Industry and Food and Drug Administration Staff, issued June 27, 2014.
[17] Food and Drug Administration, Unique Device Identification System: Small Entity Compliance Guide - Guidance for Industry and Food and Drug Administration Staff, issued August 13, 2014.
[18] Food and Drug Administration, Unique Device Identifier System: Frequently Asked Questions, Vol. 1 - Guidance for Industry and Food and Drug Administration Staff, issued August 20, 2014.
[19] Food and Drug Administration, Unique Device Identification: Direct Marking of Devices- Guidance for Industry and Food and Drug Administration Staff, issued June 26, 2015.

✓ ***Other FDA Resources***

FDA also makes available several resources on the UDI website. First, labelers and GUDID users can contact the FDA UDI Help Desk if they have questions or need assistance on UDI.[20] This feature is an online query system in which questions or requests for assistance are submitted via the web.

Additionally, the FDA also maintains its past presentations on UDI and GUDID training modules.[21] These modules are maintained on the website in various media, such as transcripts, audio, printable slides, and videos.

To generally stay-up-to date, subscribe to FDA's UDI mailing list for notifications about UDI program updates, as well as FDA's GUDID mailing list for alerts about database changes and GUDID system status updates.

Steps You Need to Take to Achieve UDI Compliance

How can you achieve UDI compliance at your organization? Determine what devices your company handles. Confirm that you are the labeler of those devices for the purposes of UDI. Evaluate the requirements and exceptions that apply to your devices. Know the due date(s) for compliance that apply to you. Finally, get familiar with the UDI resources. Although these are just the beginning steps, what you do here will be the foundation for getting it right.

Need Help With the UDI Regulation?

Our firm routinely engages with our clients in assessing their UDI requirements and creating a plan for implementing UDI. As stated above, Amy Fowler is an expert on UDI regulation and co-authored an article with Jay Crowley, the FDA official who wrote the UDI regulation. Assisting her is another associate, Beth Luoma. DuVal & Associates is also hosting a DuVal EDU Regulatory Training webinar on UDI, "***Achieving UDI Compliance and its Challenges" Webinar*** will be

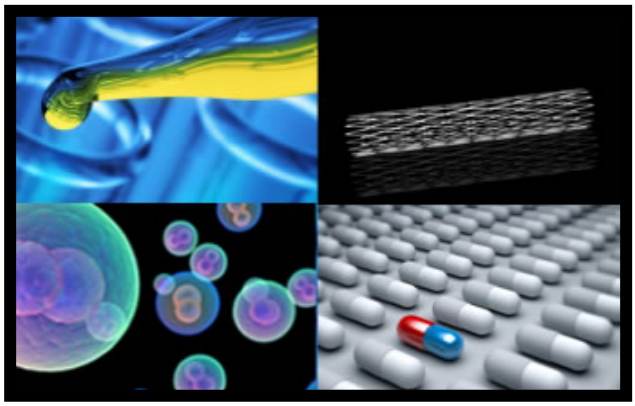
[20] U.S. Food and Drug Administration, FDA UDI Help Desk, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ucm368904.htm (last accessed Aug, 12, 2015).
[21] U.S. Food and Drug Administration, UDI Training Modules for Industry, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/ChangesbetweenUDIProposedandFinalRules/default.htm (last accessed Aug, 12, 2015).

held on Monday, September 21, 2015, 9-10:30am PST; 11-12:30pm CST; 12-1:30 pm EST.

We are also here to help you individually with your UDI needs. Whether you are starting out with your UDI processes or deep into implementation, we can advise you on your UDI requirements, provide training on UDI, and help strategize UDI for future product development.

Watch for the next **Client Alert** in our series on UDI. If you have any questions, please contact Amy Fowler at fowler@duvalfdalaw.com or by phone at (612) 338-7170 x4.

CALL ON US FOR ASSISTANCE WITH YOUR REGULATORY NEEDS



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