What you need to know about the FDA's UDI system final rule

Jay Crowley, Vice President and UDI Practice Leader at USDM Life Sciences
Amy Fowler, RAC, J.D., Associate at DuVal & Associates, P.A.

bsi.

...making excellence a habit.™

Introduction

Current unique device identification (UDI) regulation in the US and global arenas

Unique Device Identification (UDI) may look like a barcode, but it is so much more. It is the key to accessing a wealth of information for medical devices around the world. The UDI you see on the package identifies the labeller and information about that specific product, but it also ties into a database that can tell you for example, if it contains latex, whether it can go into an MRI scanner, and many other important features.

Global traceability of medical devices has been a vision for decades. It has taken 10 years of work by regulators, the medical device industry, the healthcare community and other stakeholders to turn this vision into a rule. The vision started to become a reality, with the 24 September 2013 FDA (US Food and Drug Administration) final rule on the UDI system. The Herculean effort of the device manufacturers to implement the new regulation has already begun for the US. UDI requirements for major global markets will soon be in place, including the European Union (EU) and Canada.

The intention of FDA's UDI system final rule is to provide standard device identification and associated identifying information to support various public health initiatives and most notably to support FDA's post-market surveillance (PMS) activities. These include adverse event reporting (both the specific identification of devices in individual reports as well as the ability to aggregate reports), the inclusion of specific devices in both device and disease-specific registries, as well as the inclusion of device information in large population-based data sets, such as claims data.

As companies develop and implement their UDI programmes, it is imperative to focus on agency intentions and objectives of the rule to understand how and at what level, devices should be identified throughout distribution and use and over the complete lifecycle of the device.

Having said that, the most difficult part is certainly in the implementation details of this rule and is made even more challenging when considering the diversity of organizations and the breadth of medical device types. Medical device manufacturers should approach UDI as they would any other quality system type of activity – understand the rule, develop corporate policies and procedures, and document the decisions and activities. UDI is new for everyone and as with other regulatory activities, FDA is assuming that you will appropriately apply the rule and guidance to your products, which you know best. Until more is known about how UDI is working, what works and what doesn't work, FDA will be challenged to answer specific questions about compliance.

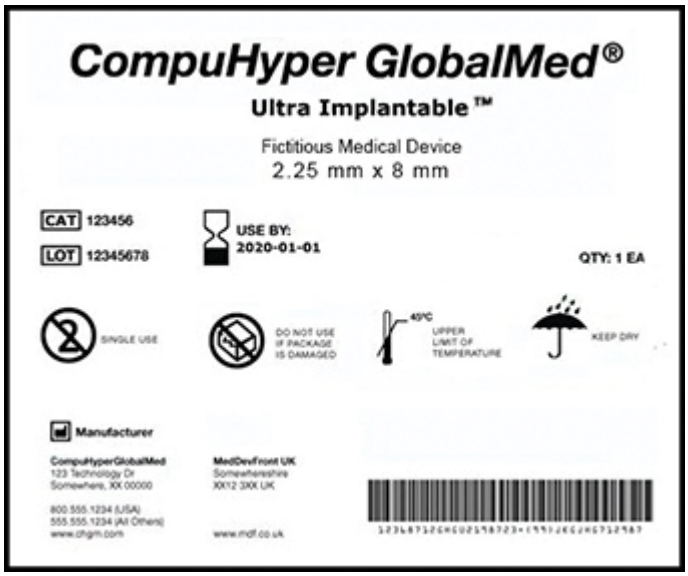


Figure 1 – Fictitious example of what a UDI would look like on a medical device label

© US Food and Drug Administration website, Medical Devices, Unique Device Identification

Table 1 – FDA's final rule – The five basic requirements

1. The label of every medical device must have a UDI.
2. Assign a globally unique, standardized identifier to devices.
3. Apply the identifier to the device's label in both plain text (human readable interpretation/HRI) and in an appropriate form of Automatic Identification and Data Capture (AIDC) technology (e.g. linear or two-dimensional barcodes).
4. Directly mark (that is, put the UDI on the device itself) those devices that are intended to be reused and reprocessed.
5. Provide identifying information (metadata) to FDA's UDI database so that other people can use and draw meaning from the identifier.

The final rule clearly states that the label of every medical device must have a UDI (see 801.20(a)). This is the general rule that must be followed. There are many exceptions and alternatives described here, but manufacturers should start with this basic notion as they work towards development and implementation of their UDI policies and procedures. The rule then goes on to state that every device package that contains a fixed quantity of a version or model must also have a UDI. Any other approach is an exception to or alternative to these requirements.

It is also useful to point out that although the term 'label' is a defined term in FDA's legislation (Section 201(k) defines 'label' as a 'display of written, printed, or graphic matter upon the immediate container of any article'), from a UDI perspective it is better to think about 'label' as a regulatory concept instead of a physical thing. For example, it may be that a manufacturer cannot fit the UDI on the current 'label' and may decide to add a separate UDI label to the device package, which is still an acceptable path. It is also important to note that UDI does not apply to other forms of labelling (e.g. instructions for use, user manuals). Although a UDI can (and probably should) be applied to labelling to associate it with the appropriate device, it is not a requirement by FDA's final rule.

Timing of due dates

Despite the request from some members of the healthcare community that FDA implement UDI for all devices within three years, FDA gave device manufacturers additional time and kept the pre-market risk-based approach.

Compliance with the UDI requirements is based on the publication of the final rule – 24 September 2013. Devices must meet the label and Global Unique Device Identification Database (GUDID) requirements by the following dates:

- 24 September 2014 – for Class III devices, such as an intraocular lens, procode HQL, and devices licensed under the Public Health Service Act;
- 24 September 2015 – for Class I and II implants and life-sustaining/life-supporting devices, such as a dialysis blood filter, procode FKJ. (There is a list, by procode, of these devices on FDA's UDI website; if your device's procode is on the list, then you need to meet the 2015 compliance date, if it is not, then you don't need to). These are sometimes called 'the FDASIA devices' (FDASIA stands for Food and Drug Administration Safety and Innovation Act of 2012);
- 24 September 2016 – for (the rest of) Class II devices, such as a cutaneous electrode, procode GXY;
- 24 September 2018 – for Class I devices that do not fall under an exception to the rule, such as a general surgery saw blade, procode GFA.

Note that manufacturers have an additional two years to meet the direct marking requirements, except for FDASIA devices, which are subject to the 2015 compliance date. The FDASIA devices are implantable, life-supporting and life-sustaining devices that are in Class I or Class II.

It is important to note that the UDI compliance dates are organized by (pre-market) risk class and not by the pre-market regulatory pathway. The risk class of a device is established when the device is initially classified, though FDA does occasionally raise or lower the classification of a device (upwards or downwards classification), which may affect other regulatory activities. When looking to understand how UDI applies to a particular device, labellers should determine the regulatory classification of the device, independent of a particular path to market.

Direct part marking

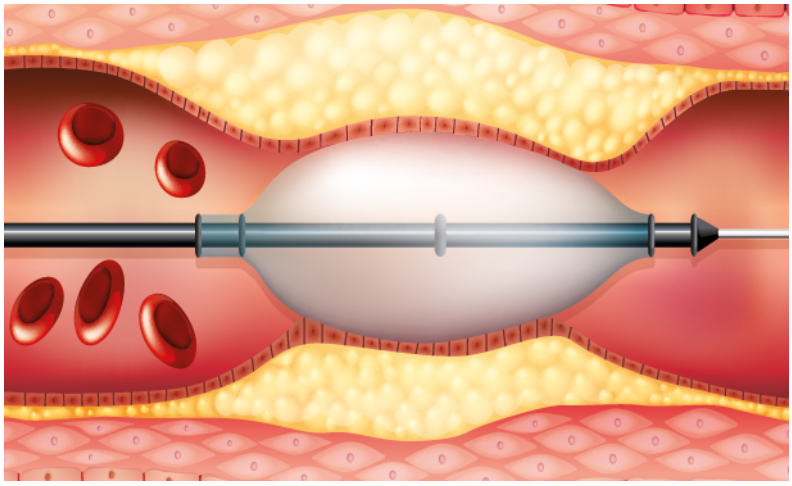
Arguably, the most significant change from the proposed to final rule was the elimination of the proposed requirement to directly mark a UDI on all implants. This decision has saved many manufacturers the huge challenge of figuring out how to etch their devices in mass production.

Convenience kits

If a UDI is applied to the 'kit' or combination product, then the individual components (or device constituent parts) are exempt from UDI label requirements. One example of a kit is an epidural tray, which has an epidural needle with wings, a loss-of-resistance syringe, an ampule of lidocaine and an ampule of saline. Since it has both drugs and devices, this epidural tray is also a combination product. Many manufacturers across the entire device industry distribute devices in 'kits' for a variety of business reasons. Different areas of the industry use different terms (e.g. trays, packs, sets) to mean essentially kits. The proposed rule had a cumbersome and confusing approach to kits and would have required kit assemblers to potentially put UDIs on finished devices that they purchased from other manufacturers. The proposed rule attempted to differentiate between these two products and created different rules for how the UDI was applied.

Combination products

A combination product with a device constituent component has special UDI provisions. An example of this type of combination product is a drug-eluting stent. If there is not a UDI on the combination product, then a UDI is required on all device constituent parts except for those that are '…physically, chemically, or otherwise combined or mixed and produced as a single entity'.[1] And, more importantly, a UDI is not required on the device constituent parts of a combination product, if the combination product's label has a UDI (and meets the other UDI requirements), whether that combination product is required to have a UDI or whether the UDI is voluntarily applied.



A drug-eluting stent

1 www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm

© BSI

The UPC exemption for OTC devices

All over-the-counter (OTC) devices are subject to UDI. These devices include the sunglasses and heating pads you can buy at a convenience store. However, Class I devices like sunglasses that are labelled with a universal product code (UPC) may utilize the UPC as the device's UDI, no additional marking is required. However, any Class II device like a heating pad sold in retail must have both a UPC and a UDI; the same goes for Class III devices sold in retail. In the proposed rule, any OTC device '... made available for purchase at a retail establishments...' would have been exempt from UDI. However, this exception also applied '...to such a [OTC] device when delivered directly to a hospital ... or other health care facility.'[2] It was never FDA's intent to exempt OTC devices, but rather to leverage the identification systems currently in place in the point of sale (POS) retail environment (that is, the UPC). Therefore, in the final rule, all OTC devices are subject to UDI.

Single-use device packaging exception

This exception allows for '... individual single-use devices, all of a single version or model, that are distributed together in a single device package ...'[3] to be excepted from individual marking as long as the package containing these individual devices has a UDI; a box of disposable needles can fit into this exception. FDA extended this exception to all classes. However, there are some important additional refining characteristics to this exception. Keep in mind that the Single-use Device (SUD) is '... intended to be stored in that device package until removed for use...'[3] and '... not intended for individual commercial distribution.'[3] This exception does not apply to implantable devices. Manufacturers using this exception must clearly document that that SUD meets all of the stated criteria.

Existing inventory exception

Existing inventory includes devices that have been manufactured, packaged and labelled prior to the class compliance date. These devices are in the manufacturer's possession or on consignment. FDA provides an additional three years that '... a finished device manufactured and labelled prior to the applicable compliance date...'[3] can be put into commercial distribution without having to meet the UDI requirements. Manufacturers stated that they did not want to have to re-label or destroy these devices, many of which have very long shelf lives and often include devices that are seldom used (e.g. very small or large sizes).

Although this is useful for many manufacturers, there are some downsides to its use. Firstly, manufacturers are likely to be putting very similar devices both with and without a UDI into commercial distribution, which could confuse downstream stakeholders and limit the benefits/utility of UDI. This will also limit manufacturer's ability to utilize UDI to improve internal processes. Moreover, manufacturers must also put robust processes to manage existing and consignment inventory to assure that it is all either used or returned prior to the end of the exception timeframe.

Compliance with FDA's UDI system

Assigning device identifiers

To date, FDA has accredited three issuing agencies (GS1, HIBCC, and ICCBBA/ISBT-128) that operate a system for assignment of UDIs. FDA is relying on these agencies to work with device manufacturers to create globally unique, standardized UDIs. Each manufacturer should evaluate which agency is the best fit for their business. It is possible that a manufacturer may want to work with more than one issuing agency. Choosing an issuing agency is primarily a business decision based on the kinds of devices and where they are distributed. It is an important decision, so weigh the options carefully. You can also switch between these organizations but there are significant issues associated with doing this.

Once you have decided which issuing agency (or agencies) you are using, you need to enumerate/assign Device Identifiers (DIs) to all of your devices and to their higher levels of packaging. There is generally a one-to-one relationship between a SKU/catalogue number and a DI. You also need to assign DIs to kits and configurable devices, which can provide some useful tools for compliance. It is important to note that only one DI from an issuing agency can be used

2 Proposed section 801.30(a)(1) , http://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf; p. 58798

3 21 CFR 801.30, General exceptions from the requirement for the label of a device to bear a unique device identifier, http://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf

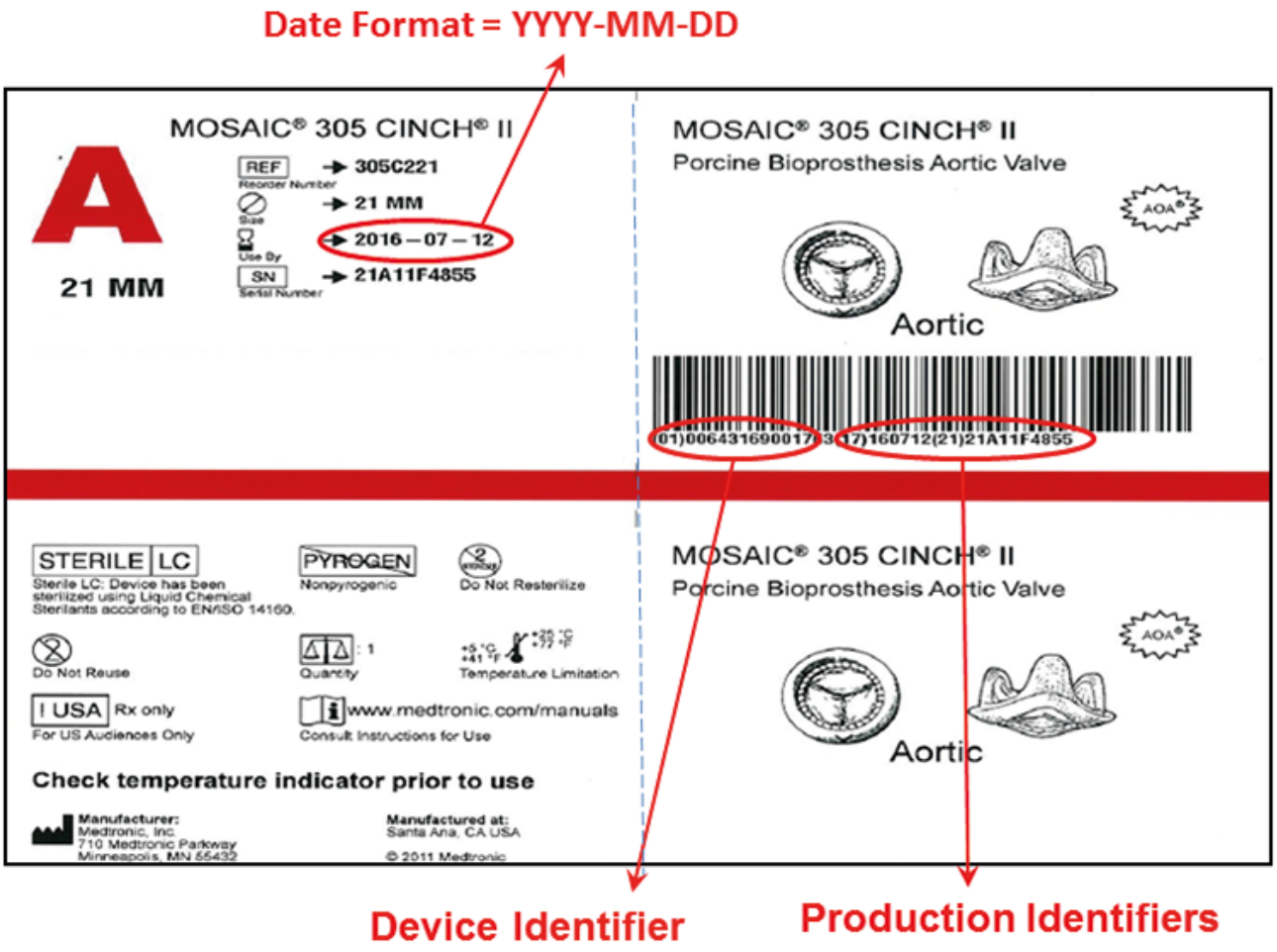
to identify a single model or version however, you may assign one DI from multiple agencies to the same device. It is also important to note that a DI can never be reused.

Moreover, each of the issuing agencies has standards or guidelines for how DIs are assigned and when a new DI can or must be assigned. And FDA's rule does not affect your use of those standards or guidelines and, in fact, implicit in the rule is the notion that you will appropriately follow and meet these guidelines. However, FDA has stated that there are three times when you must assign a new DI:

1. When you make a change to a device and you treat that changed device as a new version or model.
2. When you create a new device package.
3. When you re-label a device.

With respect to a new version or model, think about these terms as end-users view them, plus refer to the definition of version/model in the final rule. If the end-user would consider it a different or new device, then you should consider it a new 'version or model.' Assign a new DI and update the GUDID. If the end-user would not consider it a different or new device, you do not need to assign a new DI, even though you might for other business reasons. Also consider the attributes you enter into GUDID to guide your decisions for creating a new version or model.

Figure 2 – UDI compliant label – What UDI looks like on a manufacturer's product label. Human Readable (under the barcode) and AIDC format



Product of Medtronic, Inc.

With respect to a new device package, FDA's primary intention here was around the number of devices in the package and not literally in what the package looks like. So, a box of five is fundamentally different than a box of 10 and if you introduce a box of 15 you need to assign a new DI to that box. However, if you change the kind of packaging used, you do not necessarily need to assign a new DI. With respect to higher levels of packaging, the GUDID only wants to know the relationship from a quantity perspective.

If you re-label the device (put your name on it), then you need to assign your own DI and apply your own UDI and maintain a record of the original/previous DI/UDI. Even though you should retain that record internally; the GUDID does not currently have the ability to store that information. However, this is intended to be a future enhancement, so you would need to submit that information as well. Therefore, be sure that your GUDID solution is capable of capturing and storing this information.

It is also important to note that there is no inherent relationship between when a new DI is required and any FDA pre-market submission requirements. In the proposed rule, FDA used wording for when a new DI is required which was very similar to when a new 510(k) is required:

- From the UDI proposed rule: 'If you make any of the following changes to a device that is required to bear a UDI on its label … you must assign a new device identifier to the new version or model: (c) You make a change that could significantly affect the safety or effectiveness of the device' – and …
- 'A new complete 510(k) application is required for changes or modifications to an existing device, where the modifications could significantly affect the safety or effectiveness of the device…' (see FDA guidance on 510(k)

Concerns were raised that any time a new 510(k) was submitted, a new DI was required. It was not FDA's intent to tie these two activities together in this way, and in the final rule this connection does not exist. Therefore, a manufacturer may submit a new 510(k) or a premarket approval supplement for reasons that have nothing to do with device identification (e.g. indications); and conversely, a manufacturer may assign a new DI for reasons that do not affect the device's safety or effectiveness (e.g. inclusion of a CE mark).

Applying the UDI

Now that DIs have been assigned to the device, manufacturers must now apply the UDI, that is the DI and applicable product identifiers, to the label of the device. The FDA rule states that the UDI must be both in plain text (human-readable interpretation/HRI) and encoded in a form of AIDC technology. In the UDI rule, FDA did not specify any particular technology that could/should be used or not be used (technology neutrality); therefore, manufacturers are free to choose any technology that is 'approved' for use by the issuing agency that the manufacturers are working with. Having said that, UDI will not be useful if downstream users cannot scan and use it, so be sure to understand what technologies your users can use and work with them to help implement UDI. Currently, we still see many linear barcodes being used and we probably will for some time. We are starting to see more two-dimensional (2D) barcodes (e.g. data matrix, QR code) being used, both in retail and the drug and device space. However, these barcodes require an imaging scanner to be read (as opposed to the more ubiquitous laser scanners we see in retail and healthcare today). However, a 2D barcode containing all the UDI required information can be made very small and so will be very useful, particularly for very small labels. And though Radio Frequency Identification (RFID) holds promise for certain devices and packages in certain environments, adoption has been slow.

However, it is important to note especially for those manufacturers distributing devices globally that other regulators may not adopt such a neutral approach and may require or limit the AIDC technologies that can be used. Specifically, there seems to be a trend towards use of 2D barcodes, which, like the retail UPC linear barcode before it, is likely to become the standard technology over the next five years.

Label redesign

Label redesign is often needed to make room for the UDI. Many manufacturers are using this opportunity to make other label changes. Label changes can be costly, so there should be comprehensive strategies to minimize

disposal of current labels. Changes must be reflected in the device master record and all changes must be made under a formal change control process/system before implementation. If there is not room on the current device or package label and adequate space cannot be created, manufacturers should consider an additional label on the device or package that contains the UDI. In many cases this is the easiest path to compliance. A change to a label to incorporate UDI does not require the submission of a new 510(k) or PMA supplement. The addition of the UDI to the label of a Class III device should be reported in the next PMA annual report.

Higher levels of packaging

UDI is also required on higher levels of packaging, which might be called a shelf pack, carton, case, etc. The UDI applied to higher levels of packaging is no longer required when the packages are no longer homogeneous (e.g. pallet, tote). Therefore, FDA has provided an exception from UDI for what it calls a 'shipping container' – which is defined as '... a container used during the shipment or transportation of devices, and *whose contents may vary* from one shipment to another [emphasis added].' This is important, since many manufacturers use the term 'shipper' to refer to a particular type of package or packaging level – and is not necessarily synonymous with shipping container. If the contents of the shipper are homogeneous, then this level of packaging is not exempt from UDI.

Human readable interpretation /HRI

There is a lot of confusion about what is meant by the plain text version (or human readable or Human Readable Interpretation/HRI) of the UDI. It is therefore useful to understand the various use cases that the plain text version of the UDI is intended to serve:

- As we all know for the retail space, it provides a way of 'reading' the UDI if the AIDC technology fails or if the user doesn't have the technology to read it.
- It provides a very important and useful way of comparing what is in, for example, an electronic record with what is on the label of the device (that is, what is just scanned correctly compared to what is on the label).
- Although not directly related to the label, it establishes what is meant by 'The UDI.' That is, as the healthcare community and other stakeholders begin to adopt and implement UDI, it is critical that we all have the same understanding of UDI and what 'it' is and what it looks like.

Therefore, FDA expects that the full plain text version of the UDI is presented on the label exactly as the issuing agency describes it. This includes the various data or application identifiers and the properly formatted data that follows.

Standardized date format

In addition to the UDI requirements in the final rule, FDA also introduced a requirement that: dates '...intended to be brought to the attention of the user...' must be in the all numeric format YYYY-MM-DD. A day (DD) must always be included. Therefore, while making label changes to incorporate UDI, many manufacturers will also have to update the label to put expiration and manufacturing dates in this format. This format only applies to dates typically found next to the expiration (use by) or manufacturing date symbol. It does not apply to the production identifier dates that are incorporated into the UDI.

General exceptions

The UDI general rule requires the label of every device to have a UDI. However, FDA created a number of general exceptions. Any manufacturer taking advantage of these exceptions must document it in the device's design history file. A number of these have already been discussed previously (SUD packaging, existing inventory, etc.). There are a number of UDI exceptions that are typical for FDA device regulations such as custom devices, investigational devices, veterinary devices, export-only devices, devices used solely for research or teaching, and devices held by the national stockpile.

© BSI

Importantly, there are two additional exceptions for Class I devices.

1. Class I devices do not need to include their Production Identifiers (PIs) in the UDI. That is, a DI alone is sufficient as the device's UDI. FDA still expects that, as is currently done, the device would have appropriate PIs on the label however, these do not need to be encoded in the device's UDI.
2. There is a list of 527 Class I GMP-exempt product codes (procodes) – available at www.fda.gov/udi – which are completely exempt from the UDI requirements. These devices are still subject to the standardized date format.

Direct marking

There is an additional direct marking (DM) requirement for those devices intended to be used more than once (reusable) and reprocessed between patient use. As of writing, FDA has yet to clarify its definition of reprocessing for the purposes of UDI so it is prudent for manufacturers to take the broadest definition of reprocessing, that is, to assume that reprocessing includes cleaning alone, cleaning and high-level disinfection, or cleaning and sterilization. Any device meeting this criteria must have a UDI on the device itself in addition to the label and package.

There seems to be some confusion about the application of DM to certain devices, such as infusion pumps or monitors, which typically should also have the label on the device itself. In these cases, there is no additional DM requirement as long as the UDI is on the device itself. The 'labelled' UDI (on the actual device) meets both the UDI label requirement as well as the DM requirement.

It is also important to draw a distinction between DM and Direct Part Marking (DPM). DPM generally refers to an invasive (e.g. laser etching) technology used to 'engrave' a mark into a product usually with a 2D barcode. This may be required for certain devices such as reusable surgical instruments that will go through many sterilization cycles. However, FDA's requirement does not require a specific technology and in many cases a label or tag will be sufficient to meet the UDI DM requirements.

In addition to the exceptions discussed above, FDA also included a DM exception process. In this case, a manufacturer who believes that they cannot DM a device because:

- DM would interfere with the safety or effectiveness of the device;
- DM is not technologically feasible;
- the device is a reprocessed SUD; or
- the device has been previously marked.

An infusion pump

Manufacturers of devices that do not need to DM their device must note this exception in the device's design history file. Manufacturers do not need to submit an exception request to FDA.

A Class III reusable device has until 24 September 2016 to be directly marked. FDASIA devices (implantable, life-supporting and life-sustaining) do not have an additional two years due to legislative mandate. Any reusable device subject to the 2015 compliance date must be directly marked by 24 September 2015.

Specific exception or alternative placement process

In addition to the general exceptions and alternatives already described, FDA has (theoretically) created the opportunity for a manufacturer to request a specific exception or alternative placement. Though to date this process has yet to be tested, it is critical to note that the bar for these processes is very high. The reasons for this are:

- for an exception request, that the UDI requirements cannot be met because they are not technologically feasible. It does not say that they are difficult or expensive to meet, but rather that, given today's technology, they cannot be met;
- for an alternative placement request, that the alternative being suggested is sufficiently better than the base UDI requirements that it would provide for more accurate, precise, or rapid device identification – or that it would better ensure the safety or effectiveness of the device.

A request must provide adequate documentation to support the assertion. Based on these criteria, it seems unlikely that many of these requests will be granted.

FDA's global unique identification database (GUDID)

By far, the most challenging aspect of UDI compliance is the organization, transformation, maintenance and validation of the data that needs to be submitted to FDA's GUDID. FDA has published an excellent guidance document on the GUDID – which covers the overall structure of the database, how companies/organizations are managed, and the lifecycle of DI records. It is critical to note that at this time, FDA's GUDID only contains DI information (identifying information and other attributes about a device), it does not capture or contain specific production data (that is, specific lot or serial numbers). Having said that, companies should also start preparing to manage and submit PI information, particularly as other regulators develop their own UDI regulations, many of which will likely focus more heavily on traceability.

There is a robust web interface where DI records can be created, edited and published but it will be very cumbersome for any manufacturer who has more than a few hundred DIs/records to submit and manage data this way. Most manufacturers will use a system or programme to submit these records electronically, through FDA's Electronic Submission Gateway (ESG), using the Health Level 7 Structured Product Labeling (HL7 SPL) standard. FDA has published a HL7 SPL implementation guide and other guidance for those who want to develop their own electronic solution. More importantly, there are many vendors and solution providers who have various tools, both stand alone as well as those built upon various product lifecycle management and enterprise resource planning systems, which can be used to manage and submit the data to the GUDID. And GS1's GDSN-certified data pools also have a GUDID submission solution.

However, the challenge for manufacturers is to locate and manage the data. The GUDID submission is the first time that manufacturers have had to organize this type of data electronically. Much of the data does not exist electronically or as a discrete data element. Some of it may only be on the label (e.g. latex, storage conditions), some of it is likely in a RA/QA file (510(k)/PMA, listing number), and the rest likely in some sort of product specification (brand name, size).

The first step is to identify where all the data is located. Appendix B of FDA's GUDID Guidance (available at www.fda.gov/UDI) provides a detailed explanation of the data elements, their descriptions, the edit rules, the data type and length, the list of values and whether it is a new DI trigger. Use this list of data elements to develop your own data collection tool. You then need to identify who owns the specific data elements, the standard operating procedures for managing and changing the element, and how the data is validated. Any elements not currently available (gaps) need

to be identified and resolved. The data then needs to be transformed and normalized into the proper format for the database, taking into account GUDID's business rules and controlled vocabularies. Finally, a validation process needs to be developed, tested, and executed.

It is critical to note that this will be an ongoing activity as devices change and new devices are introduced, data will need to be updated and loaded. Moreover, as other regulators develop their own UDI systems, they will hopefully have some type of (hopefully similar) UDI database. This is likely to mean the addition of some local or regional data elements. Therefore, the processes and systems put in place for GUDID need to be extensible and adaptable as future needs dictate.

An overview of IMDRF's UDI system

The International Medical Device Regulators Forum (IMDRF) UDI Working Group is made up of representatives from key nations outside of the US. The group has admitted that it is closely following FDA's UDI implementation, but hoping to avoid pitfalls as FDA may discover them. The IMDRF UDI Working Group put out a UDI Guidance document, dated 09 December 2013, that can be found here: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance.pdf

The IMDRF document uses many of the same approaches as FDA, but envisions a system that is globally harmonized with a consistent approach. The EU details on UDI will be coming through the legislative process. The European Commission officially published UDI recommendations dated 5 April 2013. This non-binding document provides guidance to member states that may want to set up a UDI system. This is the only official document that is planned before publication of the Delegated Act. The timing of the Delegated Act will depend highly on the outcomes of the elections of June 2014.

Even though there is a strong push from IMDRF to have a unified global approach, there are already differences planned between the EU and US. While the US has a single primary rule (with conforming amendments to seven other sections of the Code of Federal Regulations), the EU will legislate UDI in two regulations: Medical Devices and In Vitro Medical Devices. The EU classifications are different than the classifications in the US, so requirements based on class may vary. Instead of GUDID, the EU will use EUDAMED, a pre-existing database. The types of data that will be input into EUDAMED are likely to differ somewhat from GUDID as well.

The Republic of Turkey has been a UDI pioneer and already has UDI requirements and a database in place.

Conclusions

UDI can fundamentally change and improve the way we all interact with medical devices. It can improve the way we order, purchase, securely distribute and safely and effectively use these devices. It will also inform cost and quality decisions. But more importantly, it can vastly improve our understanding of devices, through a variety of focused and effective PMS activities, including longitudinal studies. This will allow for better understanding of the long-term safety and effectiveness of specific devices, their overall risk profile, and the use of devices in specific patient populations. And when problems do arise, we will be able to quickly identify and communicate with the affected patients in ways that simply don't currently exist.

But all of this requires change. It requires device manufacturers to appropriately apply and use UDI on their device(s) and it requires everyone else involved in any aspect of device distribution and use, to adopt and implement systems to manage devices at their UDI level. And we believe that creative people will do all sorts of interesting and useful things based on a device's UDI. But this will take significant time and resources to do. However the end goal is well worth it. Just as we can't even imagine a grocery store today without UPCs and scanners , we will have a hard time remembering the device world before UDI.

Quick guide to UDI compliance

1. Read the FDA final rule:
   https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system
2. Read the GUDID guidance document:
   http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf
3. Understand your device's distribution patterns throughout the globe and keep an eye on global implementation steps as they develop for UDI.
4. Share your knowledge and educate key personnel in your company.
5. Contact your issuing agency of choice to obtain your company prefix.
6. Form your UDI implementation team. Assign UDI tasks to personnel to both tackle the transition and address the ongoing maintenance tasks.
7. Work with your issuing agency to identify and study the standards you will need to adopt.
8. Ensure you are resourced to utilize data with HL7 SPL.
9. Develop a working spreadsheet of all the devices handled by your organization. Consider how your organization will input data into GUDID and future databases. Use this tool to organize the devices first by labeller (think about situations with business partners), class of device, and compliance date. Add in all the necessary GUDID database information.
10. Ensure there is a plan to address each level of packaging that will bear UDI information.
11. Assign identification information to your devices.
12. Communicate your plans and changes both inside your organization and throughout your distribution channels.

Glossary

510(k) – US pre-market notification submission, used to gain market clearance. This is the most common path to market through FDA.

CE mark – European Union regulatory conformity mark placed on medical devices that meet the essential requirements from the applicable directive.

Convenience kit – A term that can include trays, kits, packs, etc. that have devices grouped together in a package for the convenience of the health care professional. Convenience kits can contain devices, drugs and other items that are usually used together in a particular medical procedure.

Metadata – The data that is put into GUDID for each device bearing a UDI, including information like the size of the device, whether it is for single use only, the GMDN Description, MRI compatibility, and storage and handling conditions.

NDC – National Drug Code – The US unique product identifier system for pharmaceuticals. It has 10 digits in three segments.

Procode – Product Code – Three letter classification code for pre-market devices issued by FDA. The procode of the device can be used to determine whether the device is on the list of FDASIA devices, and to quickly find the classification in order to determine the applicable compliance date.

QR code – A 2D barcode that may be used for the AIDC version of the UDI. It allows quick retrieval of information as a machine-readable optical label and has greater capacity for information compared to standard UPC barcodes.

UPC – Universal Product Code – A widely-used type of barcode that is commonly used in retail settings. It can be quickly scanned to provide information. Some medical devices that are sold over-the counter already bear a UPC.

© BSI

BSI is grateful for the help of the following people in the development of the white paper series.

Authors

Jay Crowley, USDM Life Sciences

Jay Crowley is currently Vice President and UDI Practice Leader at USDM Life Sciences, a leading global professional services firm focused exclusively on providing business process, technology and compliance solutions for the regulated life science industry. Crowley works with medical device firms to help them become UDI-compliant – and leverage that compliance to achieve benefits for themselves and their customers. Prior to joining the firm in January 2014, Crowley was Senior Advisor for Patient Safety, in FDA's Center for Devices and Radiological Health. He held a variety of positions over his nearly 27 years at FDA. Jay had primary responsibility for the development and implementation of FDA's Unique Device Identification System requirements of the 2007 FDA Amendments Act and 2012 FDA Safety and Innovation Act.

Amy Fowler, RAC, J.D., Associate at DuVal & Associates, P.A.

Duval & Associates is a law firm dedicated to counselling companies in the medical device, in vitro diagnostic, pharmaceutical, biotech, food, and nutritional supplement industries. Her practice focuses on regulatory and clinical affairs strategies, preparing domestic and foreign submissions, implementing quality systems, and working on the Unique Device Identifier (UDI) regulation. Amy has a 22-year career specializing in FDA regulatory, clinical and quality affairs working in medical devices, pharmaceutical and in vitro diagnostics.

Expert Reviewers

Jenny Gough, GS1 Specialist, Mölnlycke Health Care

Jenny has been working with GS1 standards since 1996, primarily within the retail sector but since 2006, it has been within the healthcare sector. She has not only worked with GS1 systems and processes within customer care and supply chain environments but has implemented compliant GS1 systems within two large companies within both of these industries. Jenny plays an active role in the development of harmonized UDI systems in her positions as Vice Chair of the Eucomed UDISC Task Force and Co-Chair for both the GS1 UK and GS1 Ireland Healthcare User Groups. She is also very active in spreading the word on this subject at numerous global industry conferences.

Jeffrey Secunda, Vice President of Technology & Regulatory Affairs, Advanced Medical Technology Association (AdvaMed), Washington DC

AdvaMed advocates for manufacturers of medical devices, diagnostic products, and medical information systems. Jeffrey is responsible for UDI, Postmarket Policy, and Medical Device Software issues. Jeffrey was Vice President of R&D for a medical sensor firm in Texas from 1996 to 2003. Jeffrey has more than 20 years' experience in clinical and biomedical engineering, including Massachusetts General Hospital and Children's Hospital in Boston where he founded and directed the Department of Biomedical Engineering from 1982 to 1995. Jeffrey was an Adjunct Assistant Professor of Biomedical Engineering at the Boston University School of Engineering.

Ulrike Kreysa, Vice President Healthcare, GS1 Global Office

Ulrike is a hospital pharmacist, responsible for the Healthcare sector at GS1 Global Office and works with her local colleagues in 111 countries to develop and implement GS1 standards. She manages the global user group GS1 Healthcare, which has the objective to improve worldwide patient safety and supply chain efficiencies through global standards. GS1 was the first issuing agency approved by the US FDA USA and Ulrike and her colleagues are supporting users across the world with the implementation as well as striving for a global harmonized approach to UDI.

BSI Medical Devices White Paper Advisory Panel

David Cumberland, Consultant Interventional Cardiologist and Medical Director, Prince Court Medical Centre, and Consultant at the National University Hospital, Kuala Lumpur, Malaysia

David has specialized in cardiovascular intervention since its beginnings in the late 1970s. He was a consultant at the Northern General Hospital in Sheffield, UK, with a private practice in London for many years. From 1988 to 1994 he was Consultant in Cardiovascular Studies at the San Francisco Heart Institute, and from 1994 to 2000 was Professor of Interventional Cardiology at the University of Sheffield. He is a Fellow of the Royal Colleges of Radiologists, Physicians (Edinburgh) and Surgeons; also of the American College of Cardiology and the European Society of Cardiology. He has been a regular clinical reviewer for BSI for the last eight years.

Jane Edwards, Global Product Manager, BSI

Jane holds a BSc in Chemistry and an MBA from Durham university. She has over 10 years' experience in the medical device industry, having previously worked for Coloplast in their ostomy and continence business. Jane's experience includes working within the

pharmaceutical, chemical and telecoms industries for Glaxo Wellcome, ICI and Ericsson, allowing her to bring depth of knowledge from across many industries and technologies. Her current role in BSI allows her to work with technical reviewers across all disciplines ensuring that all BSI communications are accurate and relevant. She is a member of the European Medical Writers Association.

Leo Eisner, Principal Consultant, Eisner Safety Consultants (www.EisnerSafety.com/Industry_News/)

Leo's firm specializes in helping clients through product safety, international regulatory and quality system processes. Leo is a Notified Body Auditor for NEMKO (previously for NSAI & TÜV PS). Leo is the convener of IEC SC62D JWG9 (IEC/ISO 80601-2-58) and a committee member of US TAG for TC62, SC62A and SC62D. Leo is a registered professional engineer in safety and has 28 years' experience in product safety. Leo is a member of RAPS, AAMI, ASQ, & IEEE. He's manager of the LinkedIn discussion group IEC 60601 Series – Medical Electrical Equipment.

Duncan Fatz, Independent Healthcare Consultant and writer specializing in medical devices

As a clinical trials co-ordinator for the UK's North West Thames Health Authority, a researcher for the Medical Research Council and independent consultant and lecturer, Duncan has been guiding medical device companies and their products through the clinical trial process and on to subsequent reimbursement approval in the major European markets for almost 20 years. He has written two reports on conducting medical device clinical trials for PJB Publications, and two courses for Informa Healthcare.

Navin Nauth-Misir, Regulatory Affairs Professional

Navin is Director of RA and QA for an IVD company in Wiltshire. He has 30 years' experience with medical devices and IVDs starting in the NHS. Navin worked for the UK Competent Authority investigating incidents involving critical care devices and IVDs and also as a compliance inspector. He moved to a global medical devices manufacturer where he was responsible for Quality Assurance, Regulatory Affairs and international product registration. Navin is a member of the Regulatory Affairs Professional Society (RAPS) and is also involved in the development of national and international standards. He has considerable experience working with national and European trade associations.

Mike Schmidt, Principal Consultant and owner of Strategic Device Compliance Services (www.devicecompliance.com)

Mike is a Visiting Lecturer/Honorary Academic for the Medical Device Design Master's Degree Program at the University of Auckland, New Zealand, has held the position of Secretary for IEC Subcommittee 62D since 1997 and has been a technical expert and working group in the IEC since 1992. Mr Schmidt is currently the Co-Chair of the AAMI Electrical Safety Committee.

Amie Smirthwaite, Scheme Manager and Product Technical Specialist, BSI Healthcare

Amie is a Product Technical Specialist and Scheme Manager for the Orthopaedic and Dental team with BSI Healthcare. She has been a notified body technical reviewer for 10 years, and has previously worked in both new product development and blue skies research related to orthopaedic and cardiovascular devices, and tissue engineering. She is involved in a number of medical device standards and regulatory committees, covering mechanical testing, clinical data requirements and post-market surveillance. She also delivers medical devices training for BSI, and has developed and co-authored courses in Clinical Evaluation, Risk Management (ISO 14971), Technical File Documentation, and Post-market Surveillance and Vigilance.

© BSI

Published white papers

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices – An Overview of the Likely Outcomes and the Consequences for the Market – Gert Bos and Erik Vollebregt

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance – Hassan Achakri, Peter Fennema and Itoro Udofia

Effective Post-market Surveillance – Understanding and Conducting Vigilance and Post-market Clinical Follow-up – Ibim Tariah and Rebecca Pine

Forthcoming papers

Engaging Stakeholders in the Home Medical Devices Market – Delivering personalised and integrated care now and in the future (working title), Kristin Bayer, Laura Mitchell, Sharmila Gardner and Rebecca Pine, August 2014

Growing Regulatory Requirements for Usability Engineering for Medical Devices: What's Required? (working title), Robert North, September 2014

About BSI Group

BSI (British Standards Institution) is the business standards company that equips businesses with the necessary solutions to turn standards of best practice into habits of excellence. Formed in 1901, BSI was the world's first National Standards Body and a founding member of the International Organization for Standardization (ISO). Over a century later, it continues to facilitate business improvement across the globe by helping its clients drive performance, manage risk and grow sustainably through the adoption of international management systems standards, many of which BSI originated. Renowned for its marks of excellence including the consumer recognized BSI Kitemark™, BSI's influence spans multiple sectors including aerospace, construction, energy, engineering, finance, healthcare, IT and retail. With over 70,000 clients in 150 countries, BSI is an organization whose standards inspire excellence across the globe.

BSI is keen to hear your views on this paper, or for further information please contact us here
julia.helmsley@bsigroup.com

Disclaimer

This white paper is issued for information only. It does not constitute an official or agreed position of BSI Standards Ltd. The views expressed are entirely those of the authors. All rights reserved. Except as permitted under the Copyright, Designs and Patents Act 1988, no part of this publication may be reproduced without prior permission in writing from the publisher. Whilst every care has been taken in developing and compiling this publication, BSI accepts no liability for any loss or damage caused, arising directly or indirectly in connection with reliance on its contents except to the extent that such liability may not be excluded in law. Whilst every effort has been made to trace all copyright holders, anyone claiming copyright should get in touch with the BSI at any of the addresses below.

This paper was published by BSI Standards Ltd

For more information please visit:
http://www.bsigroup.com/en-GB/our-services/medical-device-services/BSI-Medical-Devices-Whitepapers/

BSI Group Headquarters
389, Chiswick High Road
London W4 4AL
United Kingdom

T: +44 (0) 845 086 9001
E. cservices@bsigroup.com
bsigroup.com

BSI UK
Kitemark Court
Davy Avenue
Knowlhill
Milton Keynes MK5 8PP
United Kingdom

T: +44 (0) 845 080 9000
E: MK.customerservices@bsigroup.com
bsigroup.com

BSI Group America Inc
12950 Worldgate Drive
8th Floor Monument II
Herndon
VA 20170
USA

T: +1 800 862 4977 / 703 437 9000
E. inquiry.msamericas@bsigroup.com
bsiamerica.com