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Division of Dockets Management (HFA305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

***RE: Docket No. FDA-2008-N-0661, Unique Device Identification System***

Dear Sir or Madam:

AdvaMed provides this submission in response to the Food and Drug Administration's request for comments on Unique Device Identification.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,600 member companies and subsidiaries manufacture nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. More than 70 percent of our members have less than \$30 million in annual domestic sales.

AdvaMed is a strong supporter of the development and implementation of a UDI System to enhance adverse event reporting, recall completion, and improvements to medical device supply chain logistics. The primary goal of the UDI System should be to facilitate the safe use of medical devices. This goal clearly requires the commitment of device manufacturers, the FDA, and device users.

**1. Which types of devices or particular devices should be subject to the requirements of a UDI system? Which types of devices or particular devices should be exempted?**

In theory all devices should be identifiable. The UDI may approximate the best method to identify the most number of device types, but an exemption process is necessary to evaluate, and when appropriate, grant waivers for device types that can not be identified by, or will derive no patient safety benefit from UDI.

Some medical devices, by their very nature should be exempt from the UDI regulation. Custom devices are by definition devices produced for a single patient or healthcare provider, and are therefore uniquely identified by the manufacturer and known to the user. Many medical devices that are distributed through retail channels are already uniquely identified with a standard “point of sale” bar code (e.g. UPC bar code). These devices should not require an additional UDI mark on their packaging.

In general, encoded production information, such as LOT or Serial Number, should not be required in addition to the human readable production information that is already printed on the label.

In most cases, the “unit of sale” is the most appropriate packing level for placement of a UDI. However, we recognize that, in some cases that present a higher risk to patients, it may be necessary to place the UDI on the “unit of use” level. Where the unit of use packaging level has insufficient space to accommodate UDI information, or the marking would impact the form, fit, or function of the product, it should be exempt from UDI marking requirements. In those instances where the UDI can not be placed on the unit of use the UDI should appear on the level of packaging that represents the lowest stocking level of the user. This exemption for UDI on the unit of use package will be necessary for many high volume, low cost devices.

Single use devices that are components within kits should not require a unique identifier in addition to the UDI that identifies the kit itself. For example, a reagent bottle which is packaged within a IVD assay kit need not have a UDI as the UDI on the kit will allow identification of all kit components. It should be noted that the reagent bottle will bear the manufacturer’s name or logo, product reference number, LOT number, and if appropriate expiration date. The reagent bottle would only be marked with a UDI if it is packaged and distributed individually.

## **2. What are the characteristics or aspects necessary to uniquely identify a device?**

The device identifier should be comprised of a code that, when decoded through the UDI database, can identify the manufacturer and the product reference number. The production identifier, e.g. LOT, SN, or expiration date, should not be required to be encoded in the UDI bar code where this information already appears in the product labeling. Encoding production data is costly, difficult to accomplish in light of label space restraints, and of limited patient safety utility. As noted above, production data already appears on product packaging or the product itself when appropriate. The requirement for production data on product labeling should follow the current practice for medical devices and their accessories.

Machine readable and related human readable formats should be determined by the application use of the product in conjunction with the applicable UDI code standard, i.e. GS1 or HIBCC. Similarly, the decision when to change the UDI device identifier is best left to the manufacturer and healthcare sector agreements. Changes to fit, form, or function generally result in a UDI change.

Package level can be tied to the product unit of measure and can be helpful in determining the completeness of a recall, but the package level should not be confused with quantity. Use of the packing level indicator should be determined by the manufacturer. An example of the need for flexibility is that most retail pharmacies require GTIN-13 codes, which do not contain a package level indicator, for product that is scanned at “check-out” (referred to as “point of sale”).

### **3. What should be the UDI’s components?**

The GS1 (Lawrenceville, NJ/ Brussels, Belgium) and HIBCC (Phoenix, AZ) standards are robust and well known in the healthcare industry. FDA and other agencies should not institute their own proprietary standards or allow standards other than GS1 and HIBCC. The GS1 and HIBCC organizations will ensure the uniqueness of the manufacturer code. The costs that these organizations charge for enumerating manufacturer identification codes (also known as labeler or enterprise codes) should be monitored to ensure that they reflect fair market value.

- **Device Identifier (ID)**

AdvaMed supports the two element format for the static Device ID. The Device ID is comprised of a code, which is linked to the device manufacturer identity and a second code which is linked to the product reference number. Each manufacturer code is assigned, and uniqueness ensured, by the standards organizations, GS1 or HIBCC. FDA should allow for the continued use of specific NDC and NHRIC manufacturer codes that have been traditionally used on certain medical devices. The product reference number is assigned by the manufacture; while it is not necessarily the catalog number it can be linked to the catalog number in the UDI Database. The product reference number may, at the manufacturer’s discretion, incorporate a package indicator code according to the rules and standards of GS1 or HIBCC.

- **Production ID**

The production ID is a dynamic code commonly seen on device packaging as the serial number, LOT number, or expiration data. Changes to the placement of the production ID on products or packaging is extremely difficult as this information is assigned during the manufacturing process and is a critical element of the manufacturer’s Quality Management System. As stated above, there is little patient safety justification for requiring the encoding of the production ID as an element of the UDI when the information already appears on the product or its labeling.

The usefulness of the UDI should not be limited by requirements for a specific number of digits or special formatting beyond those allowed by the GS1 or HIBCC standards. The NDC, when used, can be encoded within the GS1 or HIBCC formats.

**4. Where should the UDI be placed? What should be the criteria for alternative placement of the UDI?**

Medical devices represent a universe of different sizes, materials, and manufacturing processes. In addition, device packaging is extremely varied with different materials, sizes, and processing requirements. The placement location of the UDI mark on the device packaging should be determined by the manufacturer. Industry guidelines exist that suggest the optimal and alternative locations for product identification on products and packaging.

Certain products cannot be direct part marked due to size, material, and manufacturing process factors that would negatively affect the form, fit, or function of the product. For example, coronary stents and bone screws are too tiny to be marked by any known technology; medical leeches and maggots (FDA product code NQK and NRN respectively) would be killed by application of UDI; the articulating surfaces of joint replacement components are ultra-polished during the manufacturing process and would be damaged by the etching of a UDI.

The UDI rule should allow for stacked or adjacent linear bar codes where production information is required for UDI. Non-concatenated bar codes that meet the requirements of GS1 or HIBCC will help manufacturers place UDI information onto smaller surfaces than if only concatenated bar codes were allowed.

Devices that are designed to be used for multiple patients and require reprocessing between such uses may be required to bear the complete UDI, i.e. both device ID and production ID, directly on the device. This requirement must account for devices that can not be marked directly due to size, material, or processing limitations that would compromise the safe use, form, fit, or function of the device. Requirements for direct part marking of reprocessed multiple patient use devices must acknowledge and be aligned with user capabilities.

Devices that are not designed to be reused, but are nevertheless reprocessed by third parties, must bear a new UDI identifying the reprocessor and only the reprocessor. The reprocessor's UDI should replace all instances of the original UDI of the original equipment manufacturer.

The agency should specify which devices require alternate placement by inclusion rather than mandating that all devices require alternate placement and then requiring manufacturers to petition for exclusions.

If the "unit of use" packaging level has insufficient space on such packaging to accommodate UDI information, the UDI should appear on the level of packaging that represents the lowest stocking level used by the healthcare provider. For example, if hypodermic needles are packaged in "shelf-packs" of 100 needles, then the UDI would appear on the shelf-pack of 100, not on each individual needle package.



Hypodermic needle with “unit of use” sterile package

It should be noted that each individually packaged needle will bear the manufacturer’s name or logo, product reference number, and LOT information, in human readable form. This exemption for UDI on the unit of use package will be necessary for many high volume, low cost devices.

The “unit of sale” is generally the most appropriate location for the UDI as it represents the package level from which users draw the individual devices.

To satisfy healthcare customers, manufacturers may package several devices in a “convenience kit.” Kit components may include packaged medical devices, unpackaged medical devices, or non-medical devices. Kits should be treated as a unitary medical device with a single UDI on the package. Manufacturers are required by the Quality System Regulation (21 CFR 820) to maintain a “device history record” which identifies all kit components shipped by device ID and production ID. A single UDI on the Kit will therefore be able to identify all kit components including their production information.

##### **5. How should the UDI be presented?**

The device ID should always be presented in a human readable format; it may also be presented in a machine readable format according to the GS1 and HIBCC standards. The production ID presentation format (human, machine) should be determined by the manufacturer taking into account the product category and the users’ scanning environment. For example, many laboratory analyzers use bar code data carriers to identify patient samples and test components during the performance of test analysis. Conflicts between device operation bar codes and device identification bar code in the same scanning environment could result in serious errors or device malfunction.

The Automatic Identification & Data Capture (AIDC) technology should not be specified in the UDI regulation. Limiting the AIDC technology would hamper the development of better, less expensive technologies that will meet the requirements of unique device identification in a more cost effective and efficient manner.

The selection of data carrier symbols should be made by the manufacturer. Once a provider selects an image scanner, they can scan both linear and 2D AIDC bar codes. For some devices, linear bar codes for product identifier will encourage early adoption; while 2D bar codes for production information make marking more practical.

**6. How should the UDI Database be developed and maintained?**

AdvaMed looks to FDA to establish data governance policies that will ensure the integrity and security of the UDI data.

AdvaMed recommends that FDA make available various data entry tools that will accommodate the needs of large companies with thousands of different products as well as small companies that may have only a handful of products. The web portal and business to business options that FDA has made available to electronic adverse event reporters (eMDR) are an excellent example of useful data input tools.

AdvaMed looks to FDA to be the gatekeeper for access to the UDI database. The public should have read-only access to the UDI database, similar to the public's access to the existing Registration and Listing database (FURLS). To maintain the integrity of the information in the database, only the Product/Brand Owner or its authorized agent should have access to UDI data input and editing systems. The product owner should be given the option to restrict reading access to certain of their data since some product may be customer specific or in limited distribution.

Only static information, linked to the Device ID, should be stored in the UDI database. The method by which manufacturers update UDI information or add new UDIs to the database should be consistent with manufactures' policies for communication of model number changes to the market place.

Dynamic information can not be stored in the UDI database. The storage of dynamic production information, e.g. serial or LOT numbers would require massive data storage and management systems with very little benefit towards the goal of ensuring the safe use of medical devices.

Different submission tools and formats to accommodate large and small submitters should be fully validated prior to the start of the data entry period. UDI data should be accepted from web portal, business to business batch loading tools, or certified and validated data pools. Data integrity, validation, system security, data upload and change authority should be the responsibility of FDA. Only the manufacturer or their authorized agent will be able to upload or edit data.

AdvaMed recommends a minimum mandatory dataset for the UDI database. While additional data elements may provide benefit to some users, the overall functionality of the database should not be compromised by the inclusion of a large dataset of mandatory data elements. AdvaMed recommends the following minimum data set:

- UDI code
- manufacturer identification
- brand name
- make/model
- regulatory classification code

Examples of the “regulatory classification code” are FDA Procode or GMDN. The UNSPSC is a procurement code and should not be used for regulatory classification. Additional static data elements may be included in the database. Synchronization of like data elements between FDA databases (e.g. FURLS, FAERS) should be maintained by FDA to ensure accurate data.

### **Possible Impacts of the UDI System**

We are not aware of any definitive studies that have demonstrated a patient safety benefit accruing from the use of a unique device identification system. Therefore, the implementation of the UDI system should proceed with the utmost caution to reduce the possibility of negative safety effects that may arise from the widespread and simultaneous modifications to manufacturer’s quality management systems to accommodate the UDI regulation.

Furthermore, any patient safety benefit that may be derived from UDI, such as improved adverse event reporting, will only be successful if the users of medical devices install tools and implement systems that will allow for the capture of UDI data and access to the UDI database; as well as the ongoing training of personnel that will ensure the use of UDI.

It is not possible to estimate the cost impact to manufacturing production lines without the UDI regulation specification.

However, the closer the UDI requirements are to existing product identification standards (e.g. GS1, HIBCC), the lower the cost to implement the UDI system will be to those who are currently using GS1 or HIBCC codes. AdvaMed estimates that at least 50% of manufacturers are currently using GS1 or HIBCC identification standards. The use of the GMDN nomenclature standards is very low among device manufacturers.

There will be higher cost to add static device information to UDI above the minimum dataset recommended above. There will be significantly higher cost to place UDI closer to the individual product when placement at the “unit of sale” packaging level will provide comparable patient safety benefits.

We recommend that where possible, production data be encoded in UDI only for multiple-patients reprocessible instruments.

AdvaMed recommends a three phases approach to UDI Implementation:

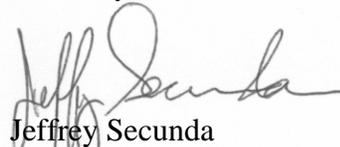
1. First - UDI Integration into Manufacturer's Quality Management System
2. Second - Establishing Marking systems in the manufacturing environment.  
This encompasses both direct part marking and label marking at various levels of packaging, as applicable to the particular product.
3. Finally - Database Entry  
Adequate time and software tools must be available to ensure accurate UDI Data entry.

### **Conclusion**

The medical device industry is ready to get to work on UDI. We ask that FDA recognize the vast differences between device types, sizes, materials, costs, and the environment in which the devices are used, and the risk to patient safety associated with the device, and provide flexibility within the regulation to accommodate these differences. In addition, adequate implementation times and tools will make the difference between an effective UDI that may have a positive impact on patient safety, and one that is broken before it even gets started.

We hope that these comments prove helpful in formulating an effective and clear regulation. If you have questions or require additional information, please contact me at (202)-434-7224 or at [jsecunda@advamed.org](mailto:jsecunda@advamed.org).

Sincerely,



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