



Food and Drug Administration [HFA-305]  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

November 8, 2006

Delivered Electronically

**Subject: Docket No. 2006N-0292:  
Unique Device Identification; Request for Comments**

Hospira Worldwide, Inc. (Hospira) is pleased to provide this comment letter in response to the FDA Docket No. 2006N-0292: Unique Device Identification (UDI): Request for Comments.

Hospira has provided comments to questions within its scope following the company background information and in the order they appeared in the Request for Comments.

**Company Background:**

Hospira is a global specialty medication delivery company dedicated to Advancing Wellness™ by developing, manufacturing and marketing products that improve the productivity, safety and efficacy of patient care. Created from the core global hospital products business of Abbott Laboratories in April 2004, Hospira has a 70-year history of service to the hospital industry and is building its future from a strong foundation as one of the largest manufacturers of hospital products in the United States. Hospira has established long-standing customer relationships that span the “continuum of care” (hospitals, home healthcare providers and long-term care facilities). Hospira manufactures and supplies a broad range of hospital products including:

- Generic and Specialty injectable drugs
- Medication delivery systems (including electronic infusion pumps)
- Infusion therapy solutions/supplies
- Critical care devices

Hospira globally manufactures over 1,100 medical devices that have the potential to be impacted by a specific UDI standard depending on its requirements.

As a manufacturer of both medical devices and generic injectable drugs for the hospital market, Hospira is able to provide the FDA with information based on our current experience with the development, use and implementation of unique device identifiers for medical devices.

## **Developing a UDI System:**

### **1. How should a UDI system be developed? What attributes or elements of a device should be used to create the UDI?**

Unique Device Identifier systems currently exist for medical devices. A number of standards organizations have been instrumental in arriving at consensus requirements for these UDI's. Their efforts and experiences should be acknowledged and utilized. Therefore, to ensure beneficiary safety, positive health outcomes, and a potential reduction in overall healthcare costs gained through supply chain efficiencies, Hospira recommends to the FDA the following regarding the development of a unique device identifier (UDI) coding standard:

- Accept currently adopted coding standards in the industry in order to take advantage of established systems.

Hospira encourages the FDA to utilize existing standards for product identification, and to develop specific guidelines for the use of these existing standards for medical devices. By adopting the currently available standards, the FDA will not need to duplicate effort to develop a standard and will assist the health care system and manufacturers to keep costs minimized. The umbrella standard that the FDA should adopt is the American National Standard: ANSI MH10.8.2. The following three medical device coding standards DOD, HIBC and GS1 comply with this standard. In addition this standard has also been endorsed by ISO, produced as ISO/IEC 15418, making this a global standard.

By adopting all these three coding standards that comply with this umbrella standard, the data structure included in the UDI will be consistent and compatible with existing hardware reading systems and technologies. For example, it is estimated that some 90% of implantable devices distributed today are coded with an existing unique identifier based on these existing standards.

Hospira, as have other companies, has made a significant investment to utilize the HIBCC coding system for barcoding medical devices. This system works well. We believe that it should continue to be used and accepted by the FDA.

Both the HIBCC and GS1 coding standards take into account international standards for medical devices and are internationally recognized. To maintaining American competitiveness in a global market, it is important that coding standards be accepted worldwide.

- The UDI system should be insensitive to the technology used to read it.

Hospira recommends that the application of a Universal Device Identification Coding standard not be specific to any automatic identification technology such as printed barcodes or RFID technologies because identification technology is rapidly changing. Certain devices may have or may require more complex technology for identification while the majority of devices may accommodate a simpler technology to utilize the UDI code. Specifying a particular UDI reading technology is time sensitive, and may not be cost effective. Capital equipment such as an infusion pump can utilize more complex ways to identify itself within a hospital Health Information System (HIS) with wireless technology. On the other hand, a device such as an I.V. fluid bag hanger is too thin to have a printed barcode on it. The technology used should be appropriate to the device health risk, device clinical utilization and its size.

The FDA commissioned ECRI August 17, 2005 White Paper: Automatic Identification of Medical Devices, Final Version recommended that the "FDA should recognize that the automatic identification technology arena is rapidly evolving..." In addition, the report stated that "there are a number of challenges and complexities associated with implementing bar codes or other automatic identification challenges for medical devices available on the market, including but not limited to, the diversity of medical devices available on the market, as one approach will not effectively support all things that are considered medical devices."

- Space is limited on many devices and the technology limits the amount of information that can be incorporated into a UDI. The elements of a UDI should be appropriate to the category or risk of the device. Therefore, the required elements must be limited.

At a minimum, the UDI coding system should include the manufacturer, the make and model of the device and if appropriate the serial number, lot number, manufacturing date or expiration date. Identifying the manufacturer and device type will go a long way to improving the capability of an electronic MDR system and assisting FDA to assure public safety of medical devices.

Additional coding elements to categorize medical devices generically across manufacturers will be difficult to do. First, there is no universally accepted generic classification of medical devices. While there are attempts to do so such as FDA procodes and GMDN, each has been shown to have its difficulties. Further, as devices may serve multiple purposes and the amount of space to contain the information is limited. There will not be enough space to place all the appropriate use codes on the label. Consider a device that is less than ½ inch is size. There will

not be enough space to place the information on the device should five linear barcodes be needed to fully characterize the categories to which it pertains. Finally, when clinically utilized, the multiple codes will not assist the hospital or FDA on how the device was ultimately used.

Further, many medical devices cannot be compared generically as unique features affect the usability and performance of the device. For example, Hospira has several medication infusion pumps designed for certain care environments and specific clinical interventions. An ambulatory pump used for Total Parenteral Nutrition (TPN) in a patient's home is not interchangeable with a Patient Controlled Analgesia (PCA) infusion pump used in the acute care hospital, yet both of these devices would fall under the "category" of "infusion pump". Categorization of medical devices would compromise patient safety, if both pumps had the same category and, therefore, viewed as interchangeable.

- The UDI coding system should exclude reimbursement information of the devices.

If the UDI was expanded to include reimbursement information, this information changes frequently and an international reimbursement standard does not exist. In addition, reimbursement information for the same medical devices may vary dependent on the site of care the device is utilized, for example, the home care versus skilled nursing facility. Inclusion of reimbursement/billing information as an element of a UDI poses the same challenges as that of attempting to include a generic classification, need for site specific use information, lack of space and the need for multiple barcodes.

The addition of reimbursement codes will create delays of availability of the device to clinicians and patients, as reimbursement codes are not consistently available at the time a new technology or device is released for use. The current CMS process for the application of Healthcare Common Procedure Codes (HCPCS) for medical devices provides a route for the identification and categorization of medical devices for provider third-party billing purposes. Today, the timing of the HCPCS coding application and determination does not coincide with the timing of the application of a UDI code on a medical device. For example, a new medical device technology should require a UDI code at market launch. The launch time may not coincide with the CMS determination of an appropriate HCPCS code for billing of that medical device.

- A UDI coding standard should be implemented on a "go-forward" basis, taking into account the installed base of FDA-approved medical devices without a UDI in the marketplace. Hospira recommends that a UDI coding standard be

implemented for newly manufactured medical devices within a 3-5 year time frame.

**2. What should be the role, if any, of FDA in development and implementation of a UDI system for medical devices? Should the system be voluntary or mandatory?**

The Agency should be an active member of the three standards organizations mentioned earlier to help establish the requirements for a UDI coding system. It is not unusual for FDA to participate in the standards development process. FDA currently participates in various standards organizations to put forth FDA requirements within the developing or modification of standards, such as the one for the standard IEC 60601-1-2 2<sup>nd</sup> Edition. All stakeholders must participate in the development of a UDI system, the regulators, the manufacturers and the health care providers.

If there are databases to be maintained, these databases should be maintained by a third-party organization or the standards organization themselves. Administrative functions or activities should not detract or subtract resources from FDA's other important activity to protect public health.

The coding system should have both required elements within reason and voluntary elements. The minimum required elements of a UDI should be the manufacturer and product identity. The remaining elements should be voluntary. Further, there may be categories of devices where even a UDI is not feasible such as on a cotton swab. The need for a UDI should include a risk based consideration. FDA already requires traceability for devices that can significantly impact the patient. Many of these devices already voluntarily have a UDI on the device itself or on the packaging serving the intended purpose of this effort.

**3. What are the incentives for establishing a uniformed standardized system of unique device identifiers?**

The main incentive for establishing a uniform device identification coding standard is patient and healthcare worker safety after there is some experience with the device. Implementation of the standard on medical devices will facilitate the identification, tracking and recall system for medical devices that have been identified to increase patient risk.

From a manufacturer's point-of-view the incentives for establishing a UDI coding standard are:

- Clear direction and guidance on requirements for product identification.
- Potential to reduce information technology expenditure.
- Potential to improve efficiency, through automation of business processes.
- Consistency.
- Improved supply chain management (from manufacturing through to end user).
- Improved product traceability.

**4. What are the barriers for establishing UDIs? What suggestions would you have for overcoming these barriers?**

Hospira endorses a UDI system that is flexible and is appropriately applied to the category of device. As in the example given by FDA regarding automobile parts or items purchased at retail or grocery store being barcoded, these items have a very simple amount of information on them. In contrast, if there is a desire to have more information on a single barcode than a single barcode can hold, there are several barriers for implementing a single UDI code requirement for all devices. They are: size limitations for certain devices, production challenges (label design and equipment), lack of an infrastructure for a public database, and increased pass-through costs.

While size is a limitation for the application of a UDI on the device itself, applying the UDI on the immediate packaging would reduce this challenge as discussed below.

Changing a UDI code system currently used on manufactured devices will impact other devices. Devices currently on the market such as the LifeCare PCA® infuser have imbedded safety software that utilizes a barcode reader to recognize specific HBICC barcoded vials. If a different UDI coding standard is required to be placed on the vials, there is an impact to not only change the vial barcode label but also the imbedded infuser software to be able to read the new barcode. With thousands of pumps in use at hospitals around the world a software upgrade will need to be done. The upgraded software must go through the QSR requirements of verification and validation.

Regarding production challenges, changing the UDI from what individual manufacturers currently have implemented will have a time and financial impact to the manufacturers that will result in pass-through costs to a health care facility. A non obvious impact is that current company mainframe computer systems and manufacturing process that utilize a specific barcode standard will have to undergo software change and validation.

To keep costs of devices down a manufacturer may batch process its labels. If the barcode now requires lot specific information, new manufacturing processes and online

printing capabilities will need to be developed and validated which will take time to accomplish. The redesigning of labeling and packaging, the purchase of printing equipment, printing and verification of UDIs, and other process changes needed to implement a UDI code outside of what is currently being done by device manufacturers will have a significant financial impact on device manufacturers and health care facilities. FDA may limit the cost burden to manufacturers and the healthcare system by phasing in the implementation of a UDI code over time and keeping the barcode required elements to a minimum, that is, the manufacturer and product I.D. A 5-year implementation phase for a UDI coding system is recommended.

Currently there is no database that would hold extended device information. To implement such a database, stakeholders would have to come together to agree on the system.

**5. Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used and the data currently provided.**

Hospira has implemented the ANS 10/HIBC data standard format on our medical devices utilizing a linear barcode. Also included below the barcode is the human readable code information. Not all devices manufactured have the barcode on the unit of use packaging. The primary reason is that there has not been a demand for it from stakeholders.

**6. Should UDIs be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?**

It is recommended that the requirement to associate a barcode to a medical device be based on reasonableness as described in question two. The data elements of the UDI should be based on the device category and be risk based. The minimum amount of information on the UDI should be the manufacturer and product I.D. Additional elements that may be helpful should be based on risk to public health. Information such as expiration date or lot number increases patient and healthcare worker safety by facilitating the identification, tracking and potential recall of the device. The devices that require tracking by FDA would fall into this category.

The FDA should address the use of UDI's when devices are reprocessed by an entity other than the original manufacturer. In addition, reprocessed single use devices (SUD) should adhere to any UDI labeling requirement. There should be a mandatory requirement for obliteration of the original manufacturer's UDI for any reprocessed single use devices.

**7. At what level of packaging (unit of use) should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?**

The need to place the UDI on the device should be based on practical limitations of the device itself and be risk based. For example by applying ink or an adhesive label on the device, these chemicals may affect the stability of the device itself. Therefore, a UDI on the outer package would be more appropriate. Likewise, where a device is small such as an intravenous tubing connector that is less than 0.5 inch in size, it will be more appropriate to apply the UDI code on the outer packaging for identification purposes.

Regarding different levels of packaging, UDI's are currently applied at varying levels of package which should be decided by the manufacturer based on a mix of changing customer (health care facility) purchasing quantity desires. There should be no requirement for case labeling.

The UDI should be based on the smallest package size that is stored or purchased. Most devices are individual packaged. Items such as non-sterile disposable examination gloves do not need to be individually wrapped and identified. Thus, any requirements should be based on reasonableness.

**8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system? (I.e.: solutions for packaging issues?)**

Technology continues to evolve. Since the application of a UDI onto a device or its immediate packaging is unique to a particular device group, the specific solutions would apply to the specific device.

There are manufacturing challenges to apply production specific information such as lot number and expiration dates during production. For example, for a low-cost high volume commodity (disposable) item, these items are commonly manufactured with preprinted barcoded labels. To switch from batch pre-printed labels, to a UDI applied on the manufacturing line requires significant investments in new technologies. In addition, any adoption of new equipment must satisfy the QSR requirements for qualifying and validating the equipment let alone the processes such as line clearance considerations.

**Implementing a UDI System:**

- 9. What is the minimum data set that should be associated with a UDI? Would this minimum data set (mds) differ for different devices? If so, how? How would the data in the mds improve patient safety? What other data would improve patient safety?**

The minimum data set should be the manufacturer identifier and the product number applied to product packaging.

Additional elements that may be helpful should be based on the risk to public health, such as expiration date or lot number. Currently, devices that must have an expiration date have these dates as part of the label in human readable form. Because this information is already listed on the device, incorporating this information as a UDI element should be voluntary. Further, any additional information that a manufacturer may want to incorporate into the UDI should be voluntary. The existing standards are flexible enough to allow this information to be added.

- 10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?**

The United States is known globally for its ability to quickly develop and manufacture high quality medical devices. An attempt to centrally register each and every device with a third party is untested. Consideration must be given that if a lot number makes a UDI unique, registration of each UDI will create administrative challenges and is not practical to get products into healthcare providers hands in a timely fashion. Therefore, it is recommended that manufacturers be required to maintain their own data sets in accordance with one of the coding standards.

All manufacturers should make their minimum data set publicly available.

- 11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself for certain devices?**

The UDI information should have a human readable string of the minimum data set. Hospira currently places the human readable alphanumeric version below the barcode symbol

The UDI should be on the level of packaging that allows for the lowest denominator of patient use at a human readable level. For example, small implantable devices such as

cardiac stents may not have enough surface space to allow for a human readable UDI code to be imprinted on the device. The UDI should be placed on the unit of use package labeling for this type of device. The required application of the UDI should be dependent on the risk classification of the device, and the size of the device.

- 12. Should the UDI be based on the use of a specific technology or be non-specific? Please explain your response. If a bar code is recommended, is a specific type of symbology preferred and if so, what type and why? Should the bar code be “compatible” with those used for the drug bar code rule? If yes, why? If not, why not?**

The UDI elements or data set should be independent of technology. Auto-identification technology is rapidly changing and is able to be cross standard compatible in many cases. For example, based on current technology, a scanner that can read a HIBCC code can read a GS1 Code; therefore, implementing the ANS10.8.2 as the UDI standard would allow current barcode scanners to be compatible.

### **Benefits and Costs**

- 13. From your perspective, what public health and patient safety benefits could be gained from having a standardized UDI system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.**

We agree that a UDI coding with a barcode system can contribute to assisting hospitals with device recalls and adverse event reporting requirements. Although, based on published reports, up to about 15% of the hospitals currently utilize barcode technology, we support health care facilities efforts to embrace this technology. If the barcodes can be scanned into an electronic adverse event reporting system, the information would help to identify the product more precisely in these reports. Hospitals that have a Hospital Information System with Bar Code Point of Care system, these systems can electronically assure recalled items are not utilized on patients

**14. From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation and use of a UDI system? Please submit detailed data to support these cost estimates.**

There are significant costs to develop and implement a UDI system particularly if a currently used code standard is not used. The major hurdle will be seen for high volume low cost disposables such as I.V. sets. Not only do labels need to be developed but also the manufacturing processes to accommodate inline application of a quality UDI code needs to be done. All these activities require the system to be in compliance with the FDA's QSR requirements. Because Hospira was a spin-off from Abbott Laboratories, we went through the experience of label changes for all our products, as the products were renamed and new product codes assigned. This activity without changes in labeling process took over two years to accomplish. Grandfathering of devices already in distribution from relabeling under a new UDI coding system is needed. Labeling process changes require additional time to be implemented correctly. Thus, it is recommended that the adoption period be three to five years for newly manufactured products.

**15. If you have already implemented a form of UDI on your medical device labeling, what investments in equipment, training and other human and physical resources were necessary to implement the use of UDIs? What factors influenced your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?**

As mentioned in previous responses, if the minimum data set comprises of the manufacturer and product I.D. and current HIBCC coding system is acceptable, the investments in equipment, training and other resources will be minimized. The addition of additional elements or a different coding system will impact the labeling, manufacturing and registration efforts and increase to the healthcare system.

**16. From your perspective, what is the expected rate of technology acceptance in implementing or using a UDI system?**

A UDI system that is flexible, recognized by standards organizations and globally recognized will allow utilization of a diverse technology to best suit the use of the device by a health care facility.



**17. From your perspective, what are the obstacles to implementing or using a UDI in your location?**

The obstacles to implementing a UDI are dependent on the UDI coding standard chosen and the number of data set elements required (if the data set is more than just the manufacturer and product I.D.)

Hospira thanks the FDA for soliciting stakeholder comments on the possibility of a unique device identification standard system. We appreciate the opportunity to share our experiences and concerns with the implementation of new regulations that affect our products and our customers. We welcome the FDA to contact us for further information and dialogue.

Sincerely,

Ray Silkaitis, R.Ph. Ph.D.  
Director, Regulatory and Scientific Affairs  
[ray.Silkaitis@hospira.com](mailto:ray.Silkaitis@hospira.com)  
224-212-4897