



November 9, 2006

**ELECTRONIC SUBMISSION**

Re: **Docket No. 2006N-0292**  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

To Whom It May Concern:

IBM is replying to Docket No. 2006N-0292 on the FDA's request for comments on unique device identification (UDI) for medical devices. IBM views automated identification as a key enabler for improving the quality of patient care, reducing medication errors, facilitating efficient recalls, reducing counterfeit drugs/devices, and driving a wide range of benefits for both industry and government. We have unparalleled experience in developing and deploying numerous automated identification and traceability solutions around the globe spanning the areas of pharmaceuticals, food, medical waste, healthcare traceability, automotive and transportation traceability.

Development of a system of unique identifiers for medical devices is a way to improve patient safety and gain additional benefits such as better management of the purchase, distribution, and use of medical devices.

IBM is pleased with the agency's efforts to enable the adoption of the UDIs for medical devices as automatic identification has great potential. We feel our relevant experience in the implementation of similar systems, especially the track and trace system IBM implemented for major pharmaceutical manufacturers and distributors, can be leveraged to create a viable and scalable system for identification and tracking of medical devices.

**DEVELOPING A SYSTEM OF UNIQUE DEVICE IDENTIFIERS**

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

Any UDI system is likely to be composed of multiple forms of data carriers - linear barcodes, 2D barcodes, passive RFID (UHF, HF, LF) active RFID, etc. - that will vary based on the significance of the application, the value of the asset being tagged, availability and skill set of the users, and the speed with which the process needs to be executed. As such the capture mechanism will vary and the key becomes how the UDI information is stored, processed, managed, and integrated with existing systems.

A standard approach should be taken to develop a unique device identification system. This standard approach will be based on an EPCglobal's Electronic Product Code (EPC) generic serial number. The pharmaceutical, consumer products and retail industries were all faced with very similar concerns and are building robust traceability systems based on the EPC Information Service and EPC Network specifications put forth by the standards organization EPCglobal. Each party maintains complete ownership and control over every read event that takes place on its property. Each party can designate how much data, if at all, it wishes to share with regulators, trading partners and the general public while the EPC Network makes access to this information secure, and as simple as using the Internet. In this way, the UDI data sets can be leveraged not only for patient safety, but also for supply chain optimization, targeted recalls, product authentication, pedigrees and shipment verification. By using the same system for medical devices and prescription drugs, hospitals can create a single infrastructure and use common applications for tracking all traceable materials. The business benefits are crucial to justifying broad adoption of a UDI system.

As has been proven in numerous other industries, attempting to embed special logic into the UDI number would be complicated and costly. The existing standards-based system that leverages EPC Information Service and EPC Network would be adequate for trillions of devices and allows for automatic rapid retrieval of product data such as make, model, revision, etc. EPCs can be used with various forms of data carriers – barcode, RFID, etc. The electronic product code standard provides a global framework for uniqueness that can scale beyond number requirements for medical devices and it is standards-based allowing any EPC member to create their own electronic product code numbers in a distributed fashion.

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

FDA should help facilitate the development of industry working groups to deliver a system for UDIs and then encourage industry adoption in order to improve patient care. UDI system should be developed under the auspices of standards organization and FDA should be an active participant in this process.

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

A standards based UDI system can generate a variety of benefits. An obvious and compelling incentive for device manufacturers is providing improved care for the patients through reduction of medical errors, reduction of stock-outs, anti-counterfeiting protection, facilitation of device recalls, and improving reporting processes. Other benefits include data exchange among trading partners to improve consignment inventory, reduce overall inventory and write-offs, better manage expiration, and reduce theft/shrink. The benefits for hospitals are improved charge capture, efficient use of hospital staff, reduced liability, and increased throughput.

IBM strongly supports open standards and is working closely with leading companies and organizations, including ISO, ETSI, EPCglobal and industry standards groups, to create an open, universal architecture for automated data capture and identification.

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

Some challenges to be addressed prior to implementation of any unique identification system are:

1. Successful involvement and participation by multiple stakeholders in the medical device value chain;
2. Fragmented market often caused by non-interoperable solutions;
3. Use of diverse identification technologies;
4. Training of users;
5. Cost of infrastructure for non-profit hospitals.

IBM suggests that medical device industry reviews the model adopted by the EPCglobal standards organization, where parties are sharing data and deriving business benefits. This model shows great promise in the area of pharmaceutical drug traceability. When using a standards-based approach, the challenges were addressed once industry started piloting and implementing automatic identification technologies at large scale.

**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.**

IBM has been working with large pharmaceutical manufacturers and distributors to implement unique identification and track and trace solution for medicine bottles, cases, totes, and pallets. The pharmaceutical industry faces the problem of counterfeit drugs and unique identifications systems (especially RFID) are an important to in solving this problem.

IBM has created a standards-based track and trace solution that uses hardware, software and services to automatically capture and track the movement of drugs through the supply chain. RFID tags are used for authentication and identification. They are attached to the products at the unit, case or pallet level and keep tabs on drugs as they move from manufacturer to wholesalers, distributors, pharmacies and hospitals.

RFID on medicine bottles and packaging is a small tag, with a microchip, which contains a unique number and acts as a license plate that transmits its unique identifier. A database uses that information to track the movement of products as they move through the supply chain. When a counterfeit drug is introduced, the system can use a range of techniques to recognize the unidentified product.

Each RFID tag contains a unique identifier that can be linked back to descriptive product information such as dosage and strength, lot number, manufacturer and expiration date. Companies can use the data to know where their products are, how long they have been in the supply chain, and which trading partner, pharmacy or hospital is currently in possession of them.

In addition to helping secure the supply chain, IBM's track and trace system also is designed to help manufacturers and distributors more easily execute drug recalls, streamline inventory and improve product forecasting. Using RFID, real-time results of unit, case and pallet movement can be fed into a data warehouse and ERP systems to monitor shipments and authenticate product transfers.

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

At some point unique identification will make sense for all medical devices. However, to make implementation of UDI system a success and to demonstrate sizeable benefits, we should encourage industry to first implement UDIs on: devices most critical for patient care such as implantable/injectable (pacemakers, defibrillators, stents, leads), devices with high value and consigned that can provide significant business benefits, devices that are often counterfeited, and devices that would benefit from having granular post-marketing visibility.

Once UDIs have been piloted and successfully implemented for many of the above-mentioned items, use should be evaluated for a broader array of devices.

**7. At what level of packaging (that is, 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?**

UDIs should be considered at the unit of use and every level of packaging hierarchy above the unit of use. For instance UDIs should be implemented at the unit of use, interpack, the case, the pallet, etc. Unit of use level is required in order to improve patient care, increase patient safety, and enable the automatic detection of counterfeits. UDIs for medical devices should leverage the existing EPCglobal standard. Electronic Product Code Information Services (EPCIS) standard creates a framework for nesting/aggregating unique identifiers (e.g. items in cases, cases on pallets). EPCIS provides standard event capture and query interfaces for obtaining and securely sharing data about unique objects in their lifecycle within and across enterprises. It enables track and trace, product authentication, diversion detection, and numerous other use cases across supply chain partners in multiple industries. Each trading partner keeps their data and trading partners only move data elements they are willing to share. This standard is already in use today in retail, healthcare and transport industries.

**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 (e.g., solutions for packaging issues)?**

We have developed an IBM track and trace solution that is already in use by large pharmaceutical manufacturers and distributors and that could be directly extended to support UDIs for medical devices. This solution revolves around use of standard based EPCIS as a means to allow data sharing among trading partners. (For more detail see response to question 5 above). The IBM solution has been implemented in live production environments without slowing down or otherwise negatively impacting existing infrastructure and systems. The solution has little to no impact on the existing processes allowing for easier implementation and user acceptance.

IBM's RFID system for pharmaceuticals is based on its WebSphere software platform. The system includes the WebSphere RFID Device Infrastructure (Edge SW), WebSphere RFID Premises Server (Middleware SW), and the EPCIS (information management repository SW) which sits between data collection devices and enterprise applications. The suite of IBM SW products enables automated data capture and sharing to facilitate many of the supply chain use cases.

**IMPLEMENTING UNIQUE DEVICE IDENTIFIERS**

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

The minimum data set that should be associated with a unique device identifier should be a serial number of 96-bit which can provide 16 trillion-trillion combinations for a given device manufacturer. Assuming that there are no privacy issues, the serial number should be accompanied by a product class number to easily identify the device. Additional data such as Lot Number and Expiration Date could be helpful in mitigating errors at the hospital. It would also help to provide better inventory and expiry management. An alternative to having all of the data on the device identifier is to only use a "license plate" number on the actual device and have database which can easily provide additional information about the device on demand.

**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 device manufacturer should set up and maintain their UDIs. The device manufacturer should use standards-based infrastructure to share UDIs with other trusted parties to which they give security privileges.

Any UDI system is likely to be composed of multiple forms of data carriers - linear barcodes, 2D barcodes, passive RFID (UHF, HF, LF) active RFID, etc - that will vary based on the significance of the application, the value of the asset being tagged and the speed with which the process needs to be executed. As such the capture mechanism will vary and the key becomes how the UDI information is stored and integrated with existing systems.

The pharmaceutical, consumer products and retail industries were all faced with very similar concerns and are moving towards the EPC Information Service and EPC Network specifications put forth by EPCglobal. In this scenario, each party maintains complete ownership and control over every read event that takes place on its property. Each party can designate how much data, if at all, it wishes to share with regulators, trading partners and the general public while the EPC network makes access to this information as simple as using the internet. In this way, the UDI data sets can be leveraged not only for patient safety, but also for supply chain optimization, targeted recalls, product authentication, pedigrees, shipment verification, etc. As demonstrated in other industries, these business benefits are crucial to justifying adoption.

### **11. Should the UDI be both human readable and encoded in an automatic technology?**

Yes. Wherever possible, a human readable form is useful as a backup in the event of system failure as well as a check for accuracy (especially in the early stages of testing and deployment.) Adoption of UDI technology and infrastructure could take several years and having the human readable form would at least allow manual data capture for the late adopters. Also see response to question 10.

### **Should the UDI be on the device itself (e.g., laser-etched) for certain devices?**

Ideally, a UDI should remain with a device for its entire lifecycle. However, this may not be practical or desirable in all situations. In many cases, such as a knee or hip replacement, the device will only be removed in the event of failure. Applying the UDI on the device packaging would provide much of the benefits and reduce many of the technology and privacy barriers.

The benefits of using an RFID tag placed on and discarded with the packaging (passive data capture, minimal opportunity for data capture error, instant visibility), outweigh the benefits of etching the UDI on the device itself (assuming the UDI is captured by a data repository for future reference.)

In other cases, embedding the UDI in or on the device - LF RFID tags in or laser etchings on a surgical instrument - may make sense. This decision depends on the value of device, the probability of losing track of the device (due to theft, hoarding, or other mechanisms) and the cost of the data carrier.

**12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response.**

The UDI should be nonspecific. Manufacturer and trading partners should agree upon specific carriers with understanding that the means of carrying UDIs will change over time as technology advances.

However, there is a certain threshold that must be met. In order to maximize the benefits of any UDI system, the underlying data carriers must support item-level serialization. It is insufficient to get to the batch or lot number as we have seen in the pharmaceutical industry. Item-level serialization would rule out linear bar codes, but not 2D barcodes, RFID or optical scans.

To future proof the investment in the system, it is crucial that the software architecture support multiple data carriers. The technologies evolve and change and new ones will be developed to meet challenges we have yet to consider. It is crucial that the software be able to pull data from these carriers and make it available in useful ways to the applications being utilized to execute a process. Similarly, the software architecture must support industry standards as these two will evolve over time. Locking into one data carrier or proprietary software system will only serve to guarantee obsolescence.

**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?**

It would be advantageous if barcode is compatible with those used for drugs since hospitals will have to deal with both devices and drugs. However, instead of waiting for another industry to define its technology path, UDI adoption should focus on piloting the necessary infrastructure to manage the data, measure process impact, and enable applications for the manufacturers and hospitals. The data carrier component represents the smallest portion of the total investment and therefore can be changed without much impact.

## **UDI BENEFITS AND COSTS**

**13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier 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.**

Benefits of a UDI system can be broken down into two major categories: benefits for the enterprise, and benefits for hospitals and patients.

1. Enterprise clients are using RFID on medical devices to instantly identify which items have been removed from a kit that's returned from a hospital, to trigger the necessary

restocking, to speed billing and quickly return the kit to circulation. The reduction in labor and improvement in payment times justifies such an investment. Similarly, with clients that provide items on consignment, simply the knowledge of where their devices are and when they are used allows them to reduce inventory, limit write-offs and speed billing.

2. For the hospital and the patient, a UDI system can have pre- and post-use benefits. Before a device is used, it can be validated as authentic, verified that it is being used on the correct patient, has not been recalled and is properly billed for. More accurate and current inventory information would also allow hospitals to take advantage of vendor managed inventory, automatically triggering replenishment, updating ordering and management systems and reducing paperwork. Post-use, a UDI system would allow manufacturers, doctors, patients and regulators to begin to track the performance of medical devices and validate their effectiveness. This would spur greater competition, innovation and improve patient safety.

Moreover, Radio frequency identification (RFID) is already proving it can cut costs by enabling more efficient and timely tracking of goods in industrial and retail supply chains. Similarly, the health care community is now seeing tremendous benefits in shipping and receiving efficiency, as well as patient identification, error reduction at point of care, medications management and real-time asset tracking.

Some examples of improving our ability to improve patient care by utilizing the latest in medical applications (such as automatic identification and RFID) are:

1. Patient Safety at Point-of-Care: Everyone has heard about tragic wrong-site, wrong-patient and wrong-procedure surgeries. Using an RFID tag in a patient's hospital bracelet, a physician can now verify the correct patient, procedure and site — prior to the start of any procedure. RFID enables caregivers to scan patient ID badges to authenticate and access appropriate levels of information and clinical data.

2. Asset tracking: RFID asset tracking solutions are helping hospitals better manage highly mobile medical equipment, such as IV pumps and wheelchairs. Asset tracking uses RFID tags to transmit location data to workstation software, which displays the data on a floor plan of the hospital. Trained staff can use the software to locate the items during their daily routines. Not only does the hospital reduce inventory and labor costs, but nurses save hours a day that they can devote to patient care.

3. Medication management: An RFID-enabled meds management solution allows a clinician to scan a patient's wristband to validate identification and review current orders from a physician. Likewise, tagged medications can be scanned to verify that patient, medication, dose and timing are consistent and accurate. In another application, RFID-enabled prescription bottles have the potential of signaling when the container is opened and can provide caregivers with a record that indicates when medicines are taken properly.

4. Clinical supplies management: As in retail, RFID in health care provides a simple solution that allows tracking of supplies from the factory to storage shelves. By enhancing supply chain efficiencies, hospitals and clinics achieve improvements in availability of supplies, less duplication and loss of equipment and savings in inventory costs.

**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.**

Setup costs involve deploying distributed infrastructure to capture and process UDI data and the training of staff to use the system. However, a UDI system for medical devices could use a similar architecture as standards-based systems that are being developed and deployed to meet drug pedigree requirements. Institutions that deploy systems to comply with drug pedigree mandates could leverage much of these system's resources and staff experience to facilitate UDI capture, processing, and reporting requirements thus minimizing incremental staff time and costs.

**15. If you have already implemented a form of unique identification 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?**

NA

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

UDI systems are one of several systems using automatic identification technologies. These systems and technologies are increasing in functionality, reliability and ease of use. The rate of acceptance of medical device UDI systems will remain slow in the next couple of years, but will increase as more systems using similar technologies show positive benefits and are deployed in healthcare environments.

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

NA

**18. For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside barcoding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?**

It is difficult to prioritize among applications that benefit patient safety.

One of the top objectives of the healthcare systems is patient safety. Some of the applications mentioned, such as systems to improve dispensing of medications, are directly related to prevention of medical errors and as such are critical.

Medical asset tracking and device identification can contribute to recapturing a significant amount of a healthcare practitioner's time so that they can focus more on improving patient safety. According to a "hospital study" quoted at the RFID, Barcoding and Emerging Technologies for Hospitals and Health Systems Conference in Philadelphia in September 2006, nurses walk 5-6 miles per day and spend 40 percent of their time looking for devices or hospital items. The business benefits from improving this process would be efficiencies and patient safety. At the same conference, a major Boston hospital quoted patient care equipment loss at \$420,000 per year and inefficiencies in time on the part of the hospital staff looking for equipment. Both improved time efficiencies and cost savings can help hospitals deliver better patient care.

**19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?**

Other industries such as pharmaceutical and retail have already demonstrated the necessary technology to capture and use UDI for inventory control and recall management. Required advancement may be in the area of hospital environment where different processes and procedures exist. The variability of the different hospitals would require some level of customization but the basic technology and infrastructure to capture and manage the data have been thoroughly tested and shown viable by other industries.

**20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?**

NA

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