

**Response to Questions issued in 8/11/06 *Federal Register***  
**Submitted by: Mobile Aspects, Inc.**  
**November 9, 2006**

The following provides responses from Mobile Aspects, Inc., to select questions from FDA as communicated in the August 11, 2006, issue of the *Federal Register*. As a brief background, Mobile Aspects provides technology solutions that store, track, and manage the utilization of medical devices and supplies within perioperative care settings by using radio frequency identification (RFID) technologies.

**FDA Request for Comment as published in the *Federal Register*, August 11, 2006:**

**III. Agency Request for Information**

In light of the potential benefits highlighted previously, FDA is interested in gathering information about the feasibility, utility, benefits, and costs associated with the development and implementation of a UDI system for medical devices. We are also interested in understanding the issues associated with the use of various automatic identification technologies (e.g., bar code, RFID). Therefore, we invite comments and available data on the following questions:

**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?***

MA Response: Mobile Aspects believes that a unique device identification system should be developed to track products at the unique item of use level. Included in this system should be information containing:

- product manufacturer
- product brand/name
- product description
- relevant product characteristics (e.g. - size, weight, color, etc.)
- lot number
- serial number
- expiration date (if applicable)

The goal of the UDI system would be to facilitate the communication of an identification unique to the specific item to be used in a clinical setting. The manner in which this is communicated can be through barcode presentation.

***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?***

MA Response: It would be highly advantageous for FDA to be involved in the development and implementation of the UDI system for medical devices. FDA can serve as a unifying body for the many disparate organizations involved in this issue and also provide a government-based organization to enforce the compliance to the UDI for manufacturers/vendors. The success with drug and pharmaceutical classification is a good example of the capabilities of the FDA in this role.

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

MA Response: In our experience implementing automated medical supply and device storage and tracking systems, the greatest incentive for care providers is the improvement in the quality of patient care. More specifically, the UDI system can help address the issue facilitating an efficient and timely approach to addressing recalls of devices. Our experience in helping our clients with this requirement in today's current environment is that it is a difficult, time consuming, and often error prone process. With the creation of a UDI system, information on device recalls can be communicated very quickly offering accurate and precise information on those devices that need to be recalled. Once that information is shared, care providers can quickly query their databases of information and identify which patients received the recalled devices and take the appropriate actions within a very short timeframe.

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

MA Response: The largest barriers to the establishment of the UDI system involve creating consensus on a single system of UDI and generating compliance from manufacturers to conform with the UDI that has been accepted. We are very hopeful the first barrier will not be terribly significant given the historical performance of FDA in facilitating the development of similar systems such as NDC. The second barrier is much more daunting, however if the consumers of these devices and supplies (e.g. - hospitals, physicians, GPOs, etc.) can exert influence on the manufacturers by showing a preference to purchase those that conform with the UDI standard, we are hopeful the device manufacturers will alter their current approaches to accommodate their consumer requests.

**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.**

MA Response: With our technology, we have leveraged a form of UDI to associate the product information collected from barcodes on the device packaging to an identification system that supports our ability to deploy RFID technology as a tracking and identification solution at the item of use level. Given the lack of uniformity in barcode classification from the manufacturers, when items are received, the barcode is scanned and that information is captured and stored within a product database and an RFID tag is produced with information on that specific, unique item. In turn, we use the RFID number from the tag as the unique identifier. When the user associates an item with the RFID tag, the RFID number is associated to the product catalog information of the item and becomes the primary key identifier of the item.

**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?**

MA Response: From a pragmatic standpoint, we feel that those devices that are involved in therapeutic treatment for patients are most appropriate for initial deployment of a UDI system. The primary rationale behind this is that these are directly related to the patient care and healing processes, and if they are subject to recall due to malfunction or other, they directly impede an ability for patients to progress in their healing goals. For diagnostic devices, due to their less invasive nature in the patient care process, they may have secondary importance when it comes to compliance with a UDI system.

**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?**

MA Response: The UDI system should apply to the unit of use that is applicable to the utilization by an individual patient for a single patient care encounter. With this level of detail, systems can be utilized to identify unit specific information as it relates to its role in the patient care and treatment process for a specific care event.

**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)?**

MA Response: Mobile Aspects has developed an RFID-based storage and tracking system for device and supply utilization. Each item is affixed with an RFID tag at the unit of use level, which facilitates the tracking of that specific item. In turn, once items are captured within the database management system, an audit trail is readily available identifying many aspects of the device current status and history. Examples are, location within the organization, dates of expiration, patients on whom devices have been used/implanted, etc. Because unit of use information is stored within an organized database structure, opportunities to query for information specific to the unit of use item are readily available.

**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?**

MA Response: The minimum data set should include:

- product manufacturer
- product brand/name
- product description
- relevant product characteristics (e.g. - size, weight, color, etc.)
- lot number
- serial number
- manufacturing date
- expiration date (if applicable)

We feel the data set should not differ between devices, but rather have uniformity as a minimum data set applicable to all. Additional data elements may be added based on the unique needs of different devices. With this minimum data set, efforts to improve patient safety can be enhanced, primarily due to having a common set of data items that enable two things:

- uniform communication protocols around device identification
- uniform querying and identification processes to expedite device removal or exchange

As an example, when devices such as ICDs implantable cardioverter-defibrillators (ICD) and cardiac resynchronization therapy defibrillators (CRT-D) were recalled recently, having a system that would provide a uniform protocol identifying those devices needed for recall would have been extremely beneficial. Once care providers possess that information, they can efficiently query the record-keeping sources (such as a database) with specific, unit of use information to identify the items they have in their current inventory or items that have been implanted within their patients.

***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?***

MA Response: The UDI and its associated minimum data set should initially be proposed by FDA, and then solicitation of feedback should be requested from the public domain. Upon receiving feedback, FDA should review and finalize the UDI system. Moving forward, the UDI system should be maintained with periodic evaluation and review facilitated by FDA. The UDI system should be made publicly available by FDA, communicated through its variety of communication channels.

***11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?***

MA Response: We feel this should be left to the discretion of the manufacturer. The issue of primary importance is identifying the UDI system and the minimum set of data required. The issue of how to represent this most effectively on the device should be left to the manufacturer's discretion given their understanding of product capabilities and the organization's business model.

***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. 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?***

MA Response: The UDI should not be based on the use of a specific technology. The issue of primary importance is identifying the UDI system and the minimum set of data required. The issue of how to represent this most effectively on the device should be left to the manufacturer's discretion given their understanding of product capabilities and the organization's business model.

As an example, as Mobile Aspects technology uses RFID to track and manage devices and supplies, it would be ideal for our clients to have all manufacturers use RFID tags to support the identification of their products. However, the reality is that most use linear barcoding today. This does not inhibit our ability to provide an RFID-based solution as we have developed a technology that can convert information rendered in a barcode format and have it re-presented in an RFID format.

## **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.***

MA Response: The public health and patient safety benefits to be gained from having a UDI system are significant. The main benefits to be cited are more timely and more accurate processes to identify items subject to recall or other adverse events.

As an example, the use of implantable stents (both drug-eluting and standard wire) for interventional cardiology procedures has risen dramatically within the last ten years. As highlighted in a report from the Society for Cardiovascular Angiography and Interventions (SCAI), approximately 800,000 stents were estimated to be used in procedures performed during 2004. Given this high volume of utilization, it is vitally important to have a uniform system to identify each of those items implanted at the unit of use level should any problems with the technology arise.

Today, the efficacy of utilizing drug-eluting stents is currently under debate. If a scenario arises that a stent is deemed defective or jeopardizes the health of a patient, the processes to uniformly communicate and identify unit of use level information for recall or other adverse purposes does not exist, creating a convoluted, confusing, and latent system of support. In the end, the patients who have been implanted with these devices suffer the ultimate risks.

***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.***

N/A

***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?***

MA Response: To support our use of RFID technology as the mechanism for identifying and tracking medical devices within the hospital, investments were made in intellectual capital and intellectual property. Resources invested to enable these capabilities is proprietary to Mobile Aspects.

In using our technology to manage their device and supplies, clients have experienced the following:

- an increase of billable charges by \$5,600 per procedure by improving accuracy in the capturing of billable charges for device utilization.
- a reduction of device expiration costs by \$250,00 by improved identification and management of expiring items
- a reduction of device inventory by \$230,000 by lowering on-hand inventory that better aligns with case volumes

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

MA Response: Based on the quantified financial, operational, and patient safety benefits identified above, the rate of technology acceptance and implementation of systems that can leverage a UDI system will be very high. Given the financial and operational issues confronting hospitals and other healthcare providers, any opportunity to experience measurable gain through technology will be seen as a valuable asset in helping them achieve performance goals.

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

MA Response: Assuming the UDI system is adopted by device manufacturers, we do not foresee significant obstacles in operationalizing the system for measurable gain to our hospital partners.

***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?***

MA Response: In our clients' experiences, hospitals are seeing a return on their investment in our technology within 8-9 months. The returns on the investment are being seen in areas that help the organization achieve revenue increases and cost decreases. When compared to other technology projects such as EHRs and bedside medication verification which have returns on investment that are non-financial, we have seen hospitals jointly pursue our projects alongside those other patient safety driven initiatives due to the compelling financial value proposition.

***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?***

MA Response: Hospitals need to invest in a technology infrastructure that automates the receiving, storage, and utilization management of devices within their organization. Technology solutions that remove the most amount of manual process to capture and track this information will have the highest level of success as they remove opportunities for manual error and latency. Investment required in these technologies will vary greatly based on size of the organization and the scope of patient care services they provide.

***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?***

N/A