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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD, 20852

RE: Docket #2006N-0292

The following comments are the general responses by the Orthopedic Surgical Manufacturers Association (OSMA) to the 20 questions put forth by FDA regarding UDI per Docket item #2006N-0292. These responses may not reflect the views of the entire membership but rather are being provided as guidelines for the Agency to consider as they contemplate the potential burdens on industry of developing a unique device identification system.

OSMA is a trade association representing the orthopedic industry. We currently have in excess of 30 member companies of various sizes and levels of maturity.

Questions for Developing a Unique Device Identification (UDI) System

**Developing a system of UDI**

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

To develop the UDI system, a working group should be assembled that includes representatives from all of the stakeholders that will be affected by the UDI System. This group should establish the key elements/information (bar code system which could contain product name, number, etc.) that should be included in the UDI system. The development of any comprehensive guidance document would require a global effort. A key item that is essential to any UDI development effort is the development and implementation of electronic patient data systems by hospitals.

- 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 fully support a comprehensive UDI program and encourage stakeholders to participate in it. FDA could potentially serve a facilitative role in the development of a global UDI

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system. They could also approach this topic with the GHTF as any action in the US would potentially have international impact especially for industry. In order for this program to work, participation in it should ideally be mandatory but statutory authority to affect all of the stakeholders impacted by UDI may not currently exist.

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

Most manufacturers currently have some type of bar coding system in place and are able to track where their product was sent. Attempts have been made in the past to establish implant registries but these have run into the same compatibility issues that loom for any UDI system. The federal government would need to perhaps offer some sort of financial incentives for both hospitals and manufacturers to offset the potentially high costs of UDI system acquisition and implementation. There are intrinsic benefits to all parties concerned if a UDI system can be established but it is difficult to place a monetary value on that benefit. Current systems are not altogether flawed either so UDI development should be allowed to proceed not only as technology advances but as it also becomes more cost-effective.

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

As stated above a key element to the success and effectiveness of any UDI system must be the implementation of electronic patient data record systems. Without these systems the use of UDI becomes almost a moot point. It could be a costly investment for hospitals and HCFs but it is critical. The federal government (HHS, etc.) may need to facilitate this activity as well and this effort should have priority over UDI so that the cart is not put before the horse. The vast majority of device manufacturers currently provide sufficient information with their products that electronic patient data systems can be developed well ahead of UDI.

For UDI implementation the standardization of data could be challenging given the variety of medical devices. One impact would be that many manufacturers would be forced to replace their entire bar coding systems to become compliant. Many hospitals and HCFs would also likely be forced to change bar code technology systems as well. These costs could potentially have a negative impact on healthcare costs nationwide. If however a functional system for maintaining electronic patient data is put in place then it will be easier to track the benefits of UDI system implementation.

- 3. 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.**

Yes, all major orthopedic device manufacturers have some type of bar code on product packaging already using the Health Industry Bar Code (HIBC). These bar codes typically contain the device's item number, lot number, the firm's name or identifier, and quantity/ UoM at a minimum. Some may also include, the manufacturing site, and expiration or manufacture date. Almost all manufacturers also supply "patient ID labels" with their devices that can be attached to patient records at the point of use; these labels may have barcodes as well. The majority of metallic and several polymeric implants also have item, serial, and/or lot numbers etched into them if their size and surface permit.

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

Yes, UDI could be considered, but not necessarily mandated, for all devices. This is also dependent upon the location and detail of the information required. Any UDI program should allow for justifiable exemptions/ exceptions. The key element here is what would be done with the information; if an electronic patient data record is maintained then this could potentially benefit device tracking in the event of a recall or other field correction.

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

Any UDI system requirements should be flexible enough to allow for technological advancements in device packaging. Generally should apply to at least the inner and outer packaging of all devices. Packaging also frequently gets removed by the hospital central storage/supply for reusable instruments and/or re-sterilizable unused implants. As long as the required information can be readily available for entry into the patient data record within a reasonable period of time then any data record should be able to accommodate this. Again this points to the importance of establishing standards for electronic patient data record systems prior to development of UDI systems.

- 6. 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)?**

As stated above orthopedic manufacturers generally have implemented HIBC bar coding of critical information on implant packaging. Some manufacturers also etch information (bar coded or otherwise) directly onto the implants. Packaging is also generally designed to allow for the reading of basic device information through any outer protective packaging layers.

## Implementing Unique Device Identifiers

- 7. What is the minimum data set that should be associated with a UDI? 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 that should be provide would be manufacture/ distributor identification, product description, item number, lot number, quantity/ UoM, and expiration, sterilization or manufacture date (as applicable). For some reusable devices such as general instruments, the need for detailed information is much less and informational requirements should be risked based. This data would improve patient safety because it would be easier for hospitals to track device use, wear, pre-determined useful life, scheduled maintenance, etc.

- 8. 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?**

UDI data would be provided by the manufacturer/ distributor to the hospital at time of purchase or use of the device in question. Once again an electronic patient data record system must be in place for the collection and maintenance of the UDI data. This patient/device data should be maintained by the hospitals but also be accessible to a national control authority (FDA, CDC, etc.) Data that has been patient information protected should also be available to manufacturers when their devices are affected. The controlling national authority should have discretionary power of what information to make available and to whom. Standard UDI information requirements can be made public through various governmental and or private routes. Release of sensitive proprietary information should be at the discretion of the manufacturer.

- 9. 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?**

Yes, the basic UDI information should be both human readable and encoded. What information is supplied on the device label could be supplied in bar code format. It is not always feasible to put the UDI information on the devise itself. Some implantable devices are extremely small while others may not provide a suitable surface for imprinting or etching this information, still other devices may risk damage if etched or if labels are directly applied. There is not a definitive need to place all UDI information directly onto all types of devices.

- 10. Should a UDI be based on the use of a specific technology (e.g., linear bar code) 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 drug bar code rule? If yes, why? If not, why not?**

The different technologies that are available should be review by "the working group" to determine which technology would be best for all. Bar codes are

already extensively used by most Orthopedic device manufacturers (HIBC format). There is no compelling reason for device and drug bar codes to be compatible but again this would be affected by an established electronic patient data record system.

### **UDI Benefits and Costs**

- 11. 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.**

A standardized UDI system could improve patient safety by possibly preventing the use of the incorrect device or device size. It would also help a hospital trace the use of a recalled device. If there is an adverse event with the device, the hospital could obtain the specific device information from the electronic record. It would also enable the hospital to track the number of times an adverse event occurred with a specific device. Again the use of UDI is tied to a previously established electronic patient data record system.

- 12. 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.**

For Hospitals and HCFs the cost to implement a UDI system would be tied to the cost of establishing an electronic patient record system. These costs involve an extensive capital investment in hardware and software not to mention the investment in human resources. To a great degree it is dependent upon the technology chosen to implement the UDI System. Even without an exact number some small hospitals may not be able to afford the initial set-up of the UDI program. Depending upon the extent of the UDI requirements the costs to manufacturers could also be very high and for some small manufacturers perhaps even prohibitively so.

- 13. 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 cost have you observed since the institution of UDIs?**

These costs and systems vary amongst the OSMA member organizations. One of the key factors in these capital systems acquisitions though is always the compatibility of the system with other systems and also its longevity.

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

Most stakeholders generally accept the concept that a reasonable and flexible UDI system would have considerable benefit. However, the costs of implementing the program without demonstrative financial benefits could slow the pace of any implementation effort. Acceptance would also be predicated upon the implementation of the aforementioned electronic patient data record system(s).

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

Investment cost for the UDI program, standardization of data, and acceptance/involvement from all respective parties. Cooperation on a global strategic level is needed for the program to be completely effective.

**16. 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 bar coding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities, and other possible advances?**

NA

**17. 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 competition purposes? How costly are these advancements?**

NA

**18. 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

OSMA appreciates the opportunity to provide comments on this issue. We look forward to working with the agency on this critical issue going forward.

Sincerely yours,



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President  
OSMA