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VIA FEDERAL EXPRESS

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

Re: Unique Device Identification Comments – Docket No. 2006N-0292

Dear Sir or Madam:

Tyco Healthcare Group LP (Tyco Healthcare) is submitting these comments in response to the FDA's notice requesting comments on unique device identification (UDI). 71 Fed. Reg. 46,233 (Aug. 11, 2006). Tyco Healthcare is a global developer, manufacturer and distributor of medical devices that vary in type, risk and complexity. Our medical device businesses generated approximately \$9 billion in fiscal year 2006. Our products include:

- Laparoscopic instruments, surgical staplers, electro-surgical instruments, vascular compression devices, needles and syringes, sharps disposal systems, enteral feeding products, pulse oximeters and ventilators;
- Medical supplies, including traditional wound care and incontinence care products; and
- Delivery systems for imaging agents.

Our products are found in almost every hospital and healthcare facility in the United States. The variety of our product offerings makes us supremely aware that not all medical devices are equally suited for one UDI system; however, we acknowledge that UDI is an important, timely issue and one that we have begun to address in different parts of our system.

We would also like to take this opportunity to thank the Agency for conducting the October 25, 2006, Public Meeting on UDI in Gaithersburg, MD. We found the presentations and discussions to be of extreme interest. We would like to provide a few observations in response to the content of the Public Meeting. First, we are concerned that the cost of implementation presented was not an accurate picture of the potential costs. The costs presented might apply for small non-integrated system delivery, but large-scale, automated, medium- and high-speed printing and verification systems tend to have an implementation cost between US\$50,000 to US\$120,000 per manufacturing line. The extent of this cost along with concomitant cost increase to the product needs to be posed against the potential patient safety benefits. Second, generally, the benefits to patient safety were taken for granted and the focus was on the cost of implementation. We believe that benefits need to be measured in a business case, prioritizing implementation based on maximum patient safety gain. Rushed implementation to cover a large manufacturer's entire

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portfolio could have adverse affects, e.g., the need to over label to meet an early implementation date introducing possibility of error or the possibility of the exclusion from a market due to added cost if UDI is required for commodity-type products. Finally, a large extent of the business case, data requirements, and carrier choice leading to an UDI or Auto ID Data Capture (AIDC) standard are being addressed by the Global Healthcare (GS1-HUG™) within a defined roadmap. A large degree of the justification and implementation strategy will be determined by this program. We believe that it would be most advantageous for the FDA to align with the GS1-HUG™ initiative to ensure the optimal global approach and most complete adoption strategy.

Response to Agency Request for Information

In response to the FDA's specific requests for information on UDI, we have reproduced the Agency's questions followed by our responses.

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?

Tyco Healthcare firmly supports the use of GS1 Standards for Auto ID applications. We believe that UDI will be most effective as a global standard and accordingly we believe that FDA should collaborate and assist in the formation of standards specifically for healthcare on a global basis rather than create its own system. We recognize and applaud FDA's participation in the initiatives under the GS1-HUG™, which are currently under way to develop a single healthcare standard. Tyco Healthcare actively participates in these activities as do a fair representation of the stakeholders. As this process advances, the standards currently in existence have been recognized by HUG as the exclusive basis for development.

The importance of aligning FDA's activities on UDI with international initiatives cannot be emphasized enough given the vast number of devices to be identified, geographical area covered, and language differences. Additionally, any UDI system should be expected to operate for an extended period of time, and would need to be scalable enough to accommodate the many thousands of individual devices that some manufacturers, including Tyco Healthcare, may produce.

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?

Tyco Healthcare believes FDA should work with the industry in the development of voluntary global standards for UDI. FDA's expertise can assist the development path and is most welcome in the external forums currently engaged in this work, specifically GS1-HUG™. In our opinion, it is paramount that standards be ratified before implementation is required. The GS1 Standards to which we refer are voluntary, yet are widely recognized. With so many stakeholders engaged in the development of healthcare-specific standards, it makes sense to allow natural adoption rather than mandating adoption. In this way, companies will realize the benefit to their processes which will, in turn, lead to wide-spread adoption once the Healthcare Standard from GS1-HUG™ is published through the Global Standards Management Process (standards ratification).

Since it is fair to say that the implementation of such a far-reaching initiative will take a significant length of time and vast amounts of money to execute correctly, incorrect or premature adoption that precedes standards development could be catastrophic for some companies. The natural progression of monitoring the adoption after the sunrise date for the standard would be a reasonable method that would allow objective proof of the concept of the standard and measure its success after a predefined time.

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

The answer to this question is necessarily specific to the particular stakeholder. For Tyco Healthcare, a multinational manufacturer of a broad range of medical devices, an important incentive is global uptake and adoption. Multiple independent and country-specific requirements could be damaging to patient safety, supply chain efficiency (especially time to market) and cost control. Moreover, we note that small facilities, such as physician's offices and nursing homes, surgery centers and small hospitals, do not have logistics systems likely to benefit from UDI. Furthermore, the investment in infrastructure, training, and maintenance of such logistics systems may outweigh the benefits for small facilities. Information System departments at hospitals are often comparatively small and stretched thin. Implementing new logistics systems would likely be an additional burden both in terms of financial and staffing impacts.

That being said, for manufacturers, we believe UDI has benefits if incorporated within manufacturing. Within manufacturing, the systems exist or can be expanded to manage the data requirements of UDI, guaranteeing validated processes to ensure the correct identification and variable information is marked on the proper device. When the UDI process is removed from manufacturing control and re-work or over labeling operations have to be developed to satisfy the demands of a particular market, mistakes are more likely. This is over and above the disadvantages of additional time and cost for re-work operations.

Ideally, if every relevant device is identified full traceability will be possible, eHealth records will be possible, recall efficiency will be improved, reimbursement and stock control will be handled effectively, and supply chain cost reductions will be achievable. It must be stressed that incorrect adoption could also have a very serious, equal and opposite effect.

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

Overall, the barriers to the use of UDI are many and diverse. One of the most significant barriers for establishing UDI relates to the diversity of devices on the market and choosing a system that works for all of them. This barrier would be compounded if individual countries or markets require different systems of UDI.

Some additional barriers include:

- Lack of an industry-wide format for identification.
- Non-universal access to bar code equipment and logistics systems.
- The sizes of some products are not large enough to permit printing of a large UDI directly on the device.

- Lack of uniformity in the shape, size, and packaging of a finished device.
- UDI data placed on the package may not be available on the individual device
- Means of attaching UDIs to an individual device may adversely impact the device performance – additional validation may be required before the UDI could be implemented.
- UDI labels attached directly to devices may create new risks, requiring updating of product risk analysis prior to implementation.
- The costs of implementing UDIs to devices are potentially enormous to medical device manufacturers, and would be classified as a “Major Rule.” The costs associated with these changes would likely be passed to the consumer, resulting in increased prices.
- Regional or country requirements which are not aligned to international standards and costs associated with changing labeling filed in various geographies.

As mentioned above, the process developing the GS1 system for specific use in healthcare is now underway. If allowed to run its course, questions such as which data, which structure and which carrier (e.g., symbology or RFID), as well as the other barriers listed above, will be answered guided by the objectives of increased patient safety and improved business accountability. It is important that limitations are not placed on development at this stage. Medical devices are extremely diverse and as a result standard setting is not a simple matter of developing a code structure and dictating use of a barcode or RFID.

We recognize the FDA and industry are at a cross-road. An inauspicious decision at this point in time could have far-reaching and possibly adverse consequences. To address and master the complexity of this topic, GS1-HUG™ has developed a detailed project plan which extends into 2008 for the publication of standards specific to healthcare. We encourage the FDA’s participation in this development, which will allow clear understanding of the decision process, complexities and barriers, and how the stakeholders, including the FDA, feel these are best overcome.

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.

Some of our divisions have established UDI with the bar coding applied directly in-line containing the Global Trade Item Number (GTIN), Lot number and expiry date (serial number is also applied in some instances) using high speed thermal transfer technology as an example. Other divisions provide 100% GS1-128 bar coding down to the unit packaging level, except where not possible due to size constraints. The data provided would be the GS1 GTIN, lot number and expiration date.

Having said this, Tyco Healthcare is a massive organization spread across the globe and implementation to this level has not been implemented across all production lines. Some UDI installations are new and some have been in existence for a period of time. Tyco Healthcare is in the process of analyzing the various market requirements and actively working on the development of the global standards with GS1-HUG™ to inform our next level of investment.

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?

The answer to this question turns on the fundamental reason for implementing UDI. Assuming that the primary goal of UDI is patient safety by reducing medical errors, UDI may not be necessary or appropriate for all devices. Issues addressed by bar coding on the drug side, e.g., drug errors, do not apply to all devices. For example, there is little chance of confusing a skin stapler with a strand of silk suture or a pulse oximeter with a ventilator. In fact, many capital equipment-type devices are already serialized and well-labeled with respect to the manufacturer and model or product number.

In addition, it may not be practical to identify some 'commodity type' devices if the cost of identification outstrips the cost of the device. Mandates to provide UDI on this type of product may ultimately result in price increases or removal of products from the market. The criticality of identification related to patient safety should be factored into the identification of commodity type devices.

In order to address those devices for which medical error is a possibility, prioritization principles should be applied to ensure that UDI addresses the most critical and highest risk devices first. Classification of devices relating to safety and the potential impact of device error must be considered for any workable 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?

The widely varying designs, functions, and applications of devices make it difficult to establish a minimum standard. What may be critical for one device may not even apply to another. For example, a gauze sponge may need identification to the unit of sale, while an orthopedic implant may need identification at the unit of use level. Moreover, it is impractical to put identifying information directly on many devices, especially single-use disposables. Many other devices already have barcodes that provide identification of manufacturer and device type on packaging, yet often times the packaging is no longer associated with the device at the time the data is needed. In short, this analysis needs to be determined based on the device type.

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)?

Specifically, certain Tyco Healthcare divisions have developed and validated methods and standards to insure that their devices are identified properly, and that the bar coding and other product identifiers are legible. In general, international standards development is addressing the rules for which engagement would be adopted, GTIN allocation rules specifically for healthcare is the first deliverable of GS1-HUG™ which defines when to apply, change or keep the same identifier.

The technology companies will make natural developments when it comes to reading multiple carriers, for instance developing a hybrid scanner to cope with high resolution requirements such as 2D Matrix combined with linear scanning for single dimension codes or other combinations of carriers that may need to be read. Ultimately, the hospital scanner or point of use needs to be able to read everything that will be presented to it, but the concept of having a selection of scanners

does not make sense and is probably not feasible from the perspective of hospitals and user facilities. Therefore, standards that drive to a common solution that are deliverable from an application and readability point of view are paramount.

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 and possible additional information is being discussed within GS1-HUG™. Because devices differ widely in routes of administration, application, and associated safety issues, it is doubtful that a standardized minimum data set could include all possible iterations. The critical safety information will still be provided with the device as it is now in printed or electronic form. For UDI, the most important information relates to the device's identification. Specifically, a reasonable minimum data requirement is the GTIN, which provides UDI based on the family of ownership. Other minimum information may include lot number and expiry date. Other data such as serial number, variable trade item count, single use or reusable etc. may also be relevant depending on the nature of the device.

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?

Under the system envisioned by GS1-HUG™, Global Data Synchronization Network (GDSN) forms the backbone of data synchronization. Maintenance will be the responsibility of the data suppliers, e.g., Tyco Healthcare. Stakeholders with a data need would be able to obtain the data from the GDSN.

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?

Where practical, UDI should be presented both as human readable information ("HRI") and machine readable; however, there are instances where HRI is not practical and should not be required. Providing the UDI on the device itself in the case of devices such as surgical instruments or orthopedic implants would be examples of where a laser etched 2D Matrix code on the devices themselves would make sense. In fact, certain market demands such as the super decontamination centers in the UK would benefit from this technology to ensure traceability.

At the present time, the GS1 general specifications determine when HRI should be applied and when there are exceptions on the need for HRI.

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?

The fundamental underpinning of the question of choosing a symbology for devices is very much based on the amount of data to be encoded. Therefore, the natural evolution of standards

development requires determining the data requirements before the symbology. In short, the data requirements must drive the symbology, not the other way round. At this point, we believe that it would be premature and possibly counterproductive to specify a particular symbology.

In our opinion, the drug bar-code rule is limited because it is impractical to code certain drugs due to size limitations. Obviously, the same argument is only amplified in the context of medical devices. Symbologies such as 2D matrix or RSS are more suited to small vial identification than bar codes and deserve consideration for identification of medical devices. Currently, the GS1 standards allow for multiple symbologies (e.g., linear, 2D, RSS) based on the requirements of the particular device. GS1-HUG™ will determine the appropriate symbology in the formation of the healthcare global standards as they are developed.

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.

One of the anticipated benefits of UDI that is frequently mentioned is that the presence of UDI will increase effectiveness in the recall and adverse event reporting requirements. We believe that UDI will be helpful to manufacturers in improving recall data because location information will be more readily obtained as track and trace gets implemented. There may also be an advantage to UDI in reporting adverse events in the case of similar or reprocessed devices by assuring assignment of the event to the correct manufacturer. Further, we are supportive of measures that might help hospitals and users accurately report adverse events and Medical Device Reports. Generally, the public health would benefit from UDI as relates to:

- ePedigree, track and trace
- Anti-counterfeiting
- Anti-divergence
- Control of inventory, e.g., elimination of expired product

Despite these general benefits to patient safety from UDI, we believe that patient safety benefits related to the identification of devices is not as clear cut as in the case of identification of drugs. The errors that drug barcoding was implemented to help eliminate, such as delivery of the wrong drug or the wrong dose, are not as obvious or as widespread for devices. Similarly, the benefits to the public health are not as obvious.

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.

The costs associated with implementing UDI can be extremely large, particularly when taking UDI to the unit of use level. One recent analysis relating to UDI requirements for one company for a single European country put the associated hardware at US\$20M. The time factor to implement such a program means the engagement of multiple projects and system validation

challenges. In addition, costs associated with implementation of related Information Systems infrastructure both at the manufacturing location and at the corporate level are enormous, but it is not possible to quantify the costs without a scope of the project. Once the business case commissioned by GS1 is completed, we believe that the very significant costs associated with implementation will be able to be quantified with some particularity.

Another practical factor to consider is implementation time. For smaller operations, it may be relatively easy to cover their portfolio of manufactured products, but for larger organizations it will take a sensible approach to the timing for UDI to implement where deemed necessary.

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?

In general, investment levels would typically average at US\$50-120K for each manufacturing line. The modifications need to incorporate in-line checking to ensure readability plus statistical sampling for measured verification.

Decision factors for implementation can include:

- Cost
- Return of investment
- Practicality to mark / label
- Supply chain management requirements

From the experience of the Tyco Healthcare divisions that have implemented UDI in the form of GS1-128 bar coding, the supply chain advantages are obvious, but the benefit to patient safety is harder to quantify and may be minimized by the relatively few U.S. institutions currently using electronic forms of inventory control for devices.

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

The rate of acceptance by manufacturers is increasing with more experimentation taking place. The possibility of comprehensive adoption would be furthered by alignment to the GS1-HUG™ program for Standards Development, which is expected to be in place by Q3/Q4 2008.

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

The obstacles to implementing a UDI system are numerous and include:

- Lack of global adoption of a singular system / standard.
- Cost of implementation.

- Need for increased staffing. Staffing is needed not only to revise the packaging artwork, but to review and approve changes, and implement the changes in the product documentation. Given the large number of products manufactured by Tyco Healthcare, this project would be of an enormous scale.
- Adverse impact to product development schedules. If implementation of a UDI system was mandated by a specific time, resources would likely have to be pulled from development projects to implement the UDI labeling changes.

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?

While this question is directed at user facilities and not at manufacturers, we would like to emphasize that the foundation for successful UDI needs to be laid on a global basis of a common standard. UDI may segue to eCatalog and eHealth records, but the basis for UDI needs to be well-considered.

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?

The eCommerce and UDI developments for hospitals require good database and data synchronization ability. Likewise, common platforms are needed regarding the external information exchange, thus, standards development in this area is also important. We note, however, that many devices distributed to hospitals are also distributed to nursing homes, physician offices, dentist offices, and other facilities that do not have ready access to bar code technology.

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?

While this is a question for user facilities, we feel that the answer to this question is very dependant on the information and infrastructure available to utilize the information which could be retrieved using UDI, given full track and trace capability.

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We appreciate the Agency's thorough examination of this topic and believe that the opportunity to comment, as well as to participate in the Agency's Public Meetings, is an excellent example of the FDA leading with the help of industry and healthcare stakeholders.

TYCO HEALTHCARE GROUP LP

By:



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