

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

Dear Sir/Ma'am:

In coordination with the Assistant Deputy Secretary of Defense for Supply Chain Integration, this office submits the attached in response to the Federal Drug Administration's request for comments on the propose Unique Device Identifier. We encourage you to adopt the existing Item Unique Identification (IUID) approach that is being successfully implemented by the Department of Defense and its Commercial Supplier Base. This approach was developed as a result of collaboration with defense and commercial industry, international partners, government agencies and is fully compliant with existing International Organization for Standards (ISO) standards for unique identification.

There is great benefit to the both this Department and the FDA to build the Unique Device Identification System on these same standards that are internationally recognized. There is strategic benefit for the FDA to leverage applicable work done by the Department of Defense Item Unique Identification (IUID) Program and to seek synergy with the supplier base. Creating a different schema for item identification that would drive requirements for a set of readers and software unique to just one commodity (medical devices) would be cost prohibitive to industry and the U.S government.

We welcome the opportunity to collaborate with the FDA on a unique device identification solution appropriate to the FDA and supportive of DoD needs.

Sincerely,

LeAntha Sumpter
Deputy Director, Program Development and
Implementation

Enclosure:
As stated

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Position Paper

**Department of Defense
Unique Identification Program Management Office
And
Electronic Business Program Management Office
Comments on the Use of a
Unique Device Identification (UDI) System**

Reference: [Federal Register: August 11, 2006 (Volume 71, Number 155)] [Page 46233-46236], DEPARTMENT OF HEALTH AND HUMAN SERVICES, Food and Drug Administration, [Docket No. 2006N-0292], Unique Device Identification, Request for Comments

Point of Contact

The point of contact for discussion regarding this response is Mr. Robert Leibrandt. His contact information is: email, Robert.Leibrandt@osd.mil; telephone, 703-695-1099. Supporting Mr. Robert Leibrandt is Mr. Mark Piper. His contact information is email: Mark_M_Piper@Keane.com; telephone: 703-848-7222.

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**Executive Summary
DoD Recommendation to FDA for Unique Device Identification**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES, Food and Drug Administration, [Docket No. 2006N-0292]

The U.S. Department of Defense (DoD) has extensive experience in implementing a unique identification program for the U.S. government. The DoD has worked with other government agencies and commercial industry partners to roll-out the DoD's unique identification (UID) program for the last four years. The DoD recommends that FDA should closely collaborate with the DoD UID Program Management Office to implement a unique device identification program.

The U. S. Department of Defense began discussions with its domestic and foreign trading partners and international coalition members in late 2002 on approaches to achieve item unique identification (IUID) spanning the 14 commodity areas, including medical equipment, purchased by the Department. The goal was to identify a schema that would ensure the global uniqueness of each item regardless of commodity type. Item Unique Identification is critical to improve asset management and accountability throughout the DoD's core mission activities and business processes. As a result of extensive deliberations, the DoD issued its IUID policy on July 29, 2003 featuring a collaborative UII solution reached with its participating domestic and foreign trading partners and international coalition members. The DoD is implementing policy and guidance that is directly applicable to your efforts toward medical Unique Device Identification.

The cornerstones of the DoD policy include the following ground rules for DoD's IUID program:

- The unique item identifier (UII) has to be globally unique and unambiguous.
- Semantics used by industry sectors have to be interoperably embraced and enabled.
- Item serialization practices used by industry sectors have to be accommodated.
- The UII construction process has to accommodate existing commercial standards that will provide global uniqueness.
- The UII should be applied to the item in such as way as to enable high capacity automated data capture – the selected and mandated data carrier is the ECC 200 2-Dimensional Data Matrix carrier.
- The UII data carrier enables high capacity automated data capture compliant with the syntax requirements of ISO/IEC 15434, Transfer Syntax for High Capacity Automatic Data Capture Media. This standard enables a common language for reading UIIs in different technologies.

The DoD IUID Program requires that the minimum data set to be marked on an item is:

- Manufacturer/Supplier
- Serial Number
- Part Number/Lot Number/Batch Number if included in the serialization schema

Because the DoD uses the IUID data, the DoD hosts and maintains an IUID Registry, where enterprises register item pedigree data. The UDI and associated pedigree and/or attribute data should be provided by the manufacturer and the manufacturer should be held accountable for data accuracy. In some cases serialization uniqueness may be guaranteed by a distributor or other

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party than the manufacturer under their Enterprise Identifier. The FDA may wish to host this database or contract it out to the private sector.

The DoD IUID Program has developed guidance and training materials, outreach and communication tools, and business rules to define the requirements and support implementation. The DoD has also worked to change the underlying standards and regulations to conform with and support IUID, including the DFARS, MIL-STD-130, and ISO 15434. Cost disadvantage may result from multiple Federal Agencies recommending non-standard methodologies. It is advantageous to the FDA and DoD that these established methodologies be utilized in the interest of public safety while considering cost control and achieving rapid adoption. Medical device manufacturers are already required to comply with IUID requirements when delivering products to the Department of Defense.

In response to the introduction of the DoD IUID program, numerous commercial companies have launched turnkey identification solutions for manufacturers that make it relatively easy for them to comply with the DoD mandate. This same technology to mark items and automatically capture that mark could be applied by medical device manufacturers in response to FDA implementation.

Position:

The Department of Defense Unique Identification Program Management Office and Electronic Business Program Management Office fully support the Food and Drug Administration embracing an international standards based unique identification solution. They encourage the FDA to adopt the existing Item Unique Identification (IUID) approach that is being successfully implemented by the Department of Defense and its Commercial Supplier Base. This approach was developed as a result of collaboration with defense and commercial industry, international partners, government agencies and is fully compliant with existing International Organization for Standards (ISO) standards for unique identification.

Significant resources have been invested on the part of industry and government over the past four years to achieve acceptance of standards that are now the foundation of the Item Unique Identification Program. There is great benefit to the FDA to build the Unique Device Identification System on these same standards that are internationally recognized. There is strategic benefit for the FDA to leverage applicable work done by the Department of Defense Unique Identification (UID) Program and to seek synergy with the supplier base.

The Department recommends FDA consider leveraging the 4 years of development that has been accomplished in the implementation of the Department of Defense IUID Policy as a solution to the UDI requirement. The DoD has collaborated with a broad range of industries, to agree on an open standard for data identification that enables one data capture infrastructure for all 14 DoD major commodity areas. Creating a different schema for item identification that would drive requirements for a set of readers and software unique to just one commodity (medical devices) would be cost prohibitive to industry and the U.S government.

The Department of Defense Unique Identification Program Management Office and Electronic Business Program Management Office recommend collaborative efforts to achieve rapid adoption of a successful FDA UDI System that is synergistic with the DoD UID Program. The DoD UID Program Management Office would welcome the opportunity to collaborate with the FDA on a unique identification solution appropriate to the FDA and supportive of DoD needs.

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Discussion of Unique Identification Program Management Office and Electronic Government Program Office Position

DoD Item Unique Identification (IUID) Program

The DoD began a program to uniquely identify, track and manage any DoD item, which meets specific criteria, in order to more effectively manage assets and achieve DoD operational success. The program was initiated in 2002 and has evolved to become known as the Item Unique Identification (IUID) Program. Since its initial establishment this approach has been adopted by other agencies including the US Coast Guard and has enjoyed broad success within both the defense and commercial sectors. To date over 700,000 items in the DoD have been identified using this approach and many more items identified as a standard business practice by industry for its own advantage.

Electronic Government Program

Item Unique Identification (IUID) will enable future integration of systems for electronic government. The Electronic Government Program encourages adoption of technologies that will enhance government business processes. These business processes include full life cycle support of items, materiel, and systems from acquisition to disposition. Unique Device Identification and Item Unique Identification will reduce the costs of doing business for government and industry by enabling standards for item identification in the following business processes:

- Procurement process
- Sales order process
- Shipping process
- Goods issue
- Production process (including refurbishment)
- Subcontracting process
- Goods receipt

Item Unique Identification Background

The Department of Defense Item Unique Identification Program includes medical and healthcare items, materiel and systems; in addition to other types of DoD items, materiel, and systems.

The IUID Program requires identification of new acquisitions and legacy items (those items already in DoD inventory or operational use). An item requires unique identification if it fulfills one of the following requirements:

- Item is serially managed
- Item is in controlled inventory,
- Item is mission essential as determined by the requiring activity;
- The requiring activity determined permanent identification is required,
- For any DoD serially managed subassembly, component, or part embedded within a delivered item, and the parent item that contains the embedded subassembly, component, or part.
- Item costs more than \$5,000

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The policy mandates that all new DoD solicitations and contracts issued on or after January 1, 2004 include a contract clause requiring the supplier to identify appropriate items with a Unique Item Identifier (UII). The following ground rules for DoD's IUID program have been established:

- The Unique Item Identifier (UII) has to be globally unique and unambiguous.
- Semantics used by worldwide industry sectors have to be accommodated.
- Item serialization practices used by worldwide industry sectors have to be accommodated.
- The UII construction process has to accommodate any existing commercial standards that will provide global uniqueness.
- The UII data carrier has to provide high capacity and accommodate the syntax requirements of ISO/IEC 15434, Transfer Syntax for High Capacity Automatic Data Capture Media.

Relevance of Unique Device Identification and Item Unique Identification

The Food and Drug Administration would serve the public interest in assurance of healthcare safety by establishing a registry similar to the DoD IUID Registry. The FDA registry must support the following:

- Collect UDI (similar to UII) and pedigree information of medical devices
- Assure availability of UDI(similar to UII) and pedigree information to healthcare users
- Provide single point of reference for Medical Devices that have assigned UDI(similar to UII) in order to ensure healthcare safety

The Item Unique Identification Program was undertaken to enhance asset identification and tracking in order to improve asset management.

Identification Techniques

In accordance with DoD IUID policy, the Unique Item Identifier for new items is to be created by the item manufacturer or supplier. The Unique Item Identifier is created in accordance with published guidelines and includes the use of DoD approved and established commercial standards that uniquely identify an item. A manufacturer may use either of two constructs to create a UII. Examples of each construct follows.

Enterprise Identifier = 0CVA5 (Commercial and Government Entity or CAGE Code)
Original Part Number = 1234
Serial Number = 674A36458

The International Organization for Standards (ISO) assigned Issuing Agency Code (IAC) can be derived using the Enterprise data qualifier. The IAC for CAGE is "D".

UII Construct 1	UII Construct 2
If the Serial Number is Unique within the Enterprise Identifier	If the Serial Number is Not Unique within the Enterprise Identifier but is Unique within the Part Number
DOCVA5674A36458	DOCVA51234674A36458

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Currently the DoD will also accept the following internationally recognized standards as Unique Item Identifier equivalents in addition to the Construct 1 and Construct 2 formats demonstrated above:

- Global Individual Asset Identifier (GIAI) for serially-managed items
- Global Returnable Asset Identifier (GRAI) for returnable assets
- ISO Vehicle Identification Number (VIN) for vehicle
- Electronic Serial Number (ESN) for cellular telephones

Identification, Description and Cataloging Distinctions

During the FDA Public Meeting on October 25, 2006 multiple concepts were presented as part of Unique Device Identification. Distinction must be made between the following often confused concepts:

- Unique Item Identifier
- Item Characteristics
- Item Catalog Number

The Unique Item Identifier is an identifier of a specific item. An example is a person's social security number.

Item characteristics describe the item. Examples are height, weight, hair color, gender and wearing a blue jacket. None of these are revealed in a person's Unique Item Identifier, the social security number.

Item Catalog Number provides a mechanism to purchase the item. The catalogue number is often referred to as the Product Code or National Stocking Number (NSN). The item catalog number (product code) for a blue jacket from one retailer is FC518-5160.

Marking an Item with Its Identifier

The Unique Item Identifier enables traceability of the item throughout its life. It also enables a record of accountability for the life of the item. In order to comply with the DoD IUID Program, an item is permanently marked or labeled with the Unique Item Identifier. The required Two-Dimensional (2D) Data Matrix is commonly used as a data carrier in pharmaceuticals, financial statements, aerospace, automotive and other sectors. The Two-Dimension Data Matrix has a checker board appearance with each uniformly spaced square cell corresponding to a data bit. The data matrix can store between 1 and 1950 characters. The data matrix can be square or rectangular and can range from 0.001 inch per side up to 14 inches per side. The data matrix is readable with current technology using tools called optical scanners. Optical scanners are also referred to as imagers. The optical scanner can translate the data matrix into human readable text and transmit the data to support systems for tracking and management.

The 2 Dimensional Data Matrix was chosen by the DoD because it supports encoding from 1 to 1950 characters and is the only common symbol that can be applied using inkjet, laser, dot-peen, chemical-etch and other techniques. The traditional linear bar code supports less than 100 characters in a much larger space. The Data Matrix also provides error correction and a higher rate of readability for marks that have been damaged.

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Use of a Two-Dimension Data Matrix enables rapid reading of a Unique Item Identifier using optical tools and eliminates human error created when a person attempts to read and transcribe a long alpha numeric string frequently found in an items serial number.

Registration of an Item for Future Tracking

Upon marking an item with the Unique Item Identifier, the manufacturer or supplier registers specified data in the DoD IUID Registry. The purpose of the IUID Registry is the following:

- Collect UII and pedigree information of tangible items owned by DoD
- Distribute UII and pedigree information to DoD users
- Provide single point of reference for DoD tangible items that have assigned Unique Item Identifiers

The information to be collected in the FDA's Unique Device Identification is similar to the DoD's Item Unique Identification. The information currently entered in the DoD IUID Registry is provided below as an example of the information to be collected in the Unique Device Identification System.

Item Unique Identification

- Concatenated UII
- Issuing Agency Code
- Enterprise Identifier
- Original Part Number
- Serial Number
- UII Type
- Description
- Batch/Lot
- Current Part Number
- Current Part Number Effective Date
- Manufacturer Identifier
- Parent Concatenated UII

Contract Information (Similar to Purchase Order Information)

- Contract Number
- Prime Contractor Identifier
- Acceptance Code
- Acceptance Date
- Acquisition Cost
- CLIN/SLIN/ELIN
- Foreign Currency Code
- Ship-to Code
- Unit of Measure

Custody Information

- CAGE
- Contract Number
- DoDAAC
- DUNS
- Received Date

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- Sent Date
- Status Flag
- Category Code (E or M)

Mark Information

- Contents
- Effective Date
- Added Or Removed
- Marker Code
- Marker Identifier
- Medium
- Values in Mark Contents

Benefits of Identification

Many of the business drivers for the DoD Item Unique Identification Program are similar to the business drivers for the Food and Drug Administration Unique Device Identification Program:

- Better value for each dollar spent
- Full accountability/Asset Management
- Adverse event reporting
- Personnel safety
- Counterfeit prevention
- Improve visibility in supply chain

The patient safety benefits of Unique Device Identification include:

- Ability to track devices in order to determine medical/surgical products with best outcomes
- Ability to track items that may contribute to infections/other adverse events
- Easier identification of recall items and location of unsafe items
- Improved tracking of key devices in patients (implants, invasive items)
- Improved timely tracking of critical equipment in hospitals
- Reduced item ordering inaccuracies and receipt delays results in more timely surgeries

Information Support Infrastructure Compatibility

The two largest suppliers of enterprise resource planning (ERP) systems are SAP, AG and Oracle Corporation. Both companies are currently building Item Unique Identification capabilities into their core product offerings. Both of these ERP companies have customers who are globalized commercial companies. Additionally both ERP companies are building interfaces with optical scanning devices and image verification devices. In order for the FDA to achieve acceptance it must utilize commercially available capabilities in Automated Identification Technology. By using the Item Unique Identification approach, acceptance by medical device manufacturers and suppliers will be rapidly achieved at reduced cost to medical device manufacturers, suppliers, and distributors.

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DoD IUID Program Management Office Recommendations for FDA Unique Device Identification System

The FDA and patient safety would benefit by adopting the same requirements and standards as the DoD IUID Program.

The FDA and patient safety would benefit by creating and managing an accessible database of attributes associated with each UDI/UII.

Marking the UDI/UII all medical devices would be beneficial to the FDA and patient safety. For consumable items a embedding the UII in the commonly accepted machine-readable code on the lowest level of packaging associated with unit of issue is recommended.

The data carrier most advantageous to the FDA UDI System and patient safety is an ECC 200 2 Dimensional Data Matrix. A human readable form of the data in proximity of the 2 Dimensional Data Matrix would also be beneficial to the FDA and patient safety.

In addition the FDA and patient safety would benefit from data standardization of item nomenclatures. Standard nomenclatures will have a similar positive impact on supply chain cost savings as the IUID program.

Additional Reference Information

Additional information is available at the Department of Defense Unique Identification Website: www.acq.osd.mil/dpap/UIID/.

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The following are the IUID and E-Government PMO responses to questions asked by the Food and Drug Administration in its Request for Comment.

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?

The Unique Device Identification system must be developed so that it enables identification of devices throughout both medical and commercial business processes and operations.

Unique Device Identification must support traditional and future surgical practices and hospital processes. Technology for identification, marking, tracking, and management of devices and items will continue to evolve. Marking methods must support appropriate clinical practice regarding environment, user skill level, and recording keeping.

The Unique Device Identification System must be commercially robust. It must identify devices in a commercial business environment, which includes mergers, acquisitions and divestitures of device suppliers. The individual device must be traceable to its source and all steps between. For example Johnson and Johnson has become a worldwide organization of over 230 companies. The Unique Device Identification System must be capable of supporting device identification for an organization as dynamic as Johnson and Johnson. The world has become a global market place utilizing a world wide supply chain. The Unique Device Identification System must support a cohesive strategy for multiple sources of supply from around the world.

The Unique Device Identification System must support life-cycle management of the asset. The pedigree information of Unique Device Identification must use a methodology that tracks the device from manufacturing to patient. This methodology includes tracking the following information through multiple organizations and systems:

- Manufacturer
- Supplier/Distributor
- Healthcare provider
- Patient

Although the DoD IUID Program was not designed exclusively for medical device and healthcare manufacturing and delivery processes it satisfies and supports them

The FDA has expressed interest in identification technology that supports identification and description of a device. Distinguishing between the identification, the description and cataloging of a device must be supported by a Unique Device Identification System. Any device identification solution must generate an identifier that is unique to that device, making the device globally identifiable and distinctive. The identification information must be separated from the descriptive information within the two-dimensional matrix. By separating the identification from the description, a system is created that supports multiple types of devices.

The Unique Device Identification system must be based on non-proprietary and open standards. Standards such as ISO 13485, Quality Management Standard for Medical Devices, must be supported by the Unique Device Identification System.

The form, fit, and function of a medical device must be retained and not be altered by the Unique Device Identification System. User training and skills for use of the Medical Device should not be altered by the Unique Device Identification System.

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It is the belief of the Department of Defense Item Unique Identification Program Management Office that the DoD IUID Program satisfies the considerations and requirements described in the previous discussion. The considerations and requirements have been documented over the past four years since the inception of the Item Unique Identification Program launched in 2002. These requirements and considerations have been gathered at scores of meetings that included the appropriate communities of interest.

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?

The FDA played a crucial role in developing a numbering scheme for pharmaceuticals (i.e., National Drug Code or NDC) that has resulted in improved patient safety and significant cost savings in both human and financial capital. We see the FDA playing the same role to bring order and utility to the medical/surgical commodity. The system should be mandatory for all manufacturers and any organization that repackages these items for resale or distribution.

Because there are multiple organizations, multiple standards, and multiple identification methods, an overarching organization is needed to provide guidance on the interaction of these varied components, as well as establish policy for the adoption of an identification system.

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

Incentives are similar to those that accrue from data standardization:

- Facilitate patient safety
 - Improve ability to recall dangerous items
 - Improve item identification to ensure the right item is ordered
 - Reduce clinical frustration with receiving wrong item and delaying surgery
 - Improve speed of item delivery to avoid treatment delay
- Reduce costs
 - Eliminate manual order rework from purchasing the wrong item
 - Improve analysis of alternative items
 - Reduce operational expense by reducing item research time
 - Improve business intelligence to enable item standardization and improve contracting actions through volume purchasing
 - Improve back office productivity by improving management of ordering, receiving, and catalog data
- Improved Operations
 - Ability to coordinate manufacture and repair of a device with required skills and qualifications of personnel
 - Report on manufacturing and repair processes to comply with federal regulations

It is desirable for Unique Device Identification to support compatibility testing between implant systems and diagnostic systems. To this end ISO 10303, Standard for the Exchange of Product Model Data is valuable and may prevent diagnostic procedures that create adverse events due to incompatibility with patient implants.

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

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It is important to understand that Unique Device Identification, based upon a company's enterprise code, part/lot/batch number, and serial number, is very similar to the standard business practices in place currently throughout industry that utilize serial numbers for identification and tracking. There are several potential barriers to implementing UDI.

- 1) The range of medical/surgical products to include equipment and consumable items is a challenge in terms of the level of unique identification and how items are managed. Different rules may be necessary for consumable vs. non-consumable to both identify (e.g., box, each, serial number, lot number, date of manufacture, etc.) and manage them (e.g., new vs. refurbished or modified).
- 2) The benefit of UDI will be limited if other associated data is not standardized. Concurrent efforts are necessary to standardize manufacturer name, item nomenclature, packaging, etc.
- 3) Manufacturers will resist the UDI out of fear that their products will become commoditized. Manufacturers must not be threatened that their competitive advantage in the market place is diminished by Unique Device Identification.
- 4) Device manufacturers and suppliers are driven by profitability. Manufacturers will have to be convinced that UDI provides them the opportunity to improve the management of their products thus improving their bottom line.
- 5) Manufacturers and industry groups may have their own identification systems and be reluctant to change. A coordinated effort is necessary to harmonize across the various systems to minimize the disruption to current practices while driving toward a global solution.

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.

Unique Device Identification is currently in use by medical device manufacturing and repair facilities. Many constructs in use conform to the Department of Defense Item Unique Identification constructs with no modification or only simple modifications to include the Enterprise Identifier. The technology includes use a two dimensional data matrix to speed and assure correct identification of data. Also, 2 dimensional data matrices are in use by the United States Postal Service for identifying, tracking and managing mail.

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?

UDI should be considered for all devices including equipment and consumables. Any device that must be tracked for performance and quality assurance should be identified with a Unique Device Identification. Other industries, like the aircraft industry, utilize related technologies, such as Serial Number Tracking (SNT), to assure passenger protection and safety. Additionally this type of initiative has proven the value of standard/synchronized data that allow market efficiencies saving them millions of dollars annually, get new products to market more quickly, and improve the efficiency of product recalls.

The technology exists today to enable marking all types and sizes of items. The FDA must examine threshold values for devices to determine if threshold values are a consideration in creating policy and regulatory requirements.

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?

For consumable items, it is recommended that a UDI be assigned to the unit of issue (e.g., box, can, each). For non-consumable items such as equipment the individual item must receive a UDI. If the UDI will be the basic identification for counterfeit and recall actions, the UDI marking also should include both machine readable and human readable component to allow clear identification of the device. As patient records and device records become more electronic, the UDI must be entered into a patient's electronic health record, and would allow for retrospective studies for efficacy or patient notification.

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)?

The DoD is implementing policy and guidance that is directly applicable to medical Unique Device Identification. The DoD is rolling out the Item Unique Identification (IUID) Program. The Item Unique Identification Program utilizes a two-dimensional data matrix that is machine readable. Along side the two-dimensional data matrix human readable marking (alphanumeric characters) is encouraged where possible. The Department of Defense Item Unique Identification Program encourages the use of international standards and commercial off-the-shelf products to minimize problems.

The DoD IUID Program has developed guidance and training materials, outreach and communication tools, and business rules to define the requirements and support implementation. The DoD has also worked to change the underlying standards and regulations to conform with and support IUID, including the DFARS, MIL-STD-130, and ISO 15434. It is advantageous to the FDA and DoD that these established resources be utilized in the interest of public safety while considering cost control and achieving rapid adoption.

In response to the introduction of the DoD IUID program, numerous commercial companies have launched turnkey identification solutions for manufacturers that make it relatively easy for them to comply with the DoD mandate. It is expected that much of this same technology could be applied by medical device manufacturers in order to respond to the FDA UDI program.

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 DoD IUID Program requires that the minimum data set to be marked on an item is:

- Manufacturer/Supplier
- If Applicable: Part Number/Lot Number/Batch Number
- Serial Number

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The Registry for the DoD IUID Program recognizes the following minimum data set. A minimum data set that would enable tracking and management of devices in the event of a device recall would include:

- UDI
- Manufacturer
- Part Number
- Serial Number
- Lot or Batch Number
- Unit of Measure or Quantity
- Item Description
- Date of Manufacture
- Expiration Date

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 UDI and associated pedigree and/or attribute data should be provided by the manufacturer and the manufacturer should be held accountable for data accuracy. The FDA may wish to host this database or contract it out to the private sector. Because the DoD is the user of the IUID data, the DoD hosts and maintains the IUID Registry, where enterprises register item pedigree data.

Public availability of UDI data needs to be addressed in the context of a need-to-know-basis and right-to-know-basis. Additionally, proprietary technology, non-disclosure of market information, and the competitive advantage of commercial organizations must be respected and protected.

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?

The Unique Device Identification System must include machine readable identification due to space limitations frequently encountered on medical devices. The DoD IUID Program calls for a machine readable two dimensional data matrix as the data carrier for the Unique Item Identifier. Use of Automated Identification Technology reduces human error caused by manual entry of data. Applying the UDI directly on the item versus using a label is preferable for some applications. Marking methods should be commensurate with the environmental conditions in which the device will be used, the size of the item, how it is issued and stored, and to ensure that product structural integrity is maintained.

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?

It is recommended that the FDA Unique Device Identification Program adopt a 2-Dimensional Data Matrix instead of a linear barcode similar to the DoD IUID program requirements. The 2 Dimensional Data Matrix is less susceptible to loss of data in the event that is damaged, than one-dimensional bar codes used to comply with the drug barcode rule. Data carrier durability is more important for equipment devices than for medical/surgical consumables and pharmaceuticals; however, consistency is also important. Many optical scanners are able to read both data matrices

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and linear barcodes. Therefore compatibility should not be an issue. In addition, optical scanner technologies are more prevalent in the healthcare industry than other Automated Information Technologies (AIT) such as Radio Frequency Identification (RFID). The 2-Dimensional Data Matrix is currently in use by some medical device manufacturers.

The FDA must examine threshold values for devices to determine if threshold values are a consideration in creating policy and regulatory requirements. There is merit in identifying what potential threshold parameters may include such as volume produced, cost, product life span, etc. The DoD IUID Program has considered threshold values in development of its policy.

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.

Key to any recall system is the ability to quickly identify, locate, and remove the recalled item from use. Its removal must also be reported. The Unique Device Identification System will allow those responsible to quickly and unquestionably process the recall. However, automation is required in order to reap the full benefit of the UDI in this process. An automated system should tell one where the item is located or to whom it is issued without having to physically scour the hospital for it. Ultimately, if the UDI is ever recorded in a patient's electronic health record, an automated system will be able to reveal instantly whom the item was used on or implanted in.

Internal to the operations of a medical device manufacturer or repairer, Unique Device Identification will improve the operations coordinating device identification, personnel certification and manufacturing/repair tool utilization. This will benefit the public health and patients with increased confidence and reduced 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.

Experience within the DoD indicates that from the first kick off meeting to the time that the first item is marked takes approximately one year. This implementation time does not require previous experience with Automated Identification Technology. Below is information gathered on a Unique Identification Project. Similar data was collected on three other projects.

Project: Equipment Marking

- Cost Metrics:
 - Items marked: 8,000 by 4 marking stations
 - Recurring Cost per item: \$10 to \$20
- Investment per Marking Station: \$59K
 - Equipment: Laser \$30K and \$10K Verifier
 - Installation: \$15K
 - Software: \$4K
- Training: 1 week
- Project Implementation
 - Ramp up time: 1st meeting to 1st mark = 1 Year

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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?

Information is contained in the answer to question 14.

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

For the DoD, implementation and acceptance will be immediate. Our expectation is that the FDA UDI System will be acceptable to the DoD as an IUID equivalent and we would be able to use it in our existing system to immediately identify equipment items.

Some current metrics on the DoD Item Unique Identification Program as of November 1, 2006 are as follows:

- Over 700,000 items entered in IUID Registry
- 65% of items registered by small commercial operations
- DoD industry supply chain includes companies of widely varying size:
 - \$250,000 companies
 - \$30 billion corporations
- Performed cost analysis of marking parts:
 - Repetitive manufacturing < \$0.20 per item
 - Non repetitive manufacturing \$10-\$20 per item

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

One large obstacle is organizational resistance to change. In every organization there is resistance to change. The ability to overcome this resistance makes the organization a technology leader or a technology follower.

Many device manufacturers and suppliers are comprised of multiple divisions that are structured as islands separate from each other. Another type of company in the medical device supply chain is the distributor that functions only as a warehouse and shipping point for medical devices. Frequently, little knowledge sharing takes place across these organizations. Additionally, departments within a division may be in competition with each other. This also prevents knowledge sharing. Both these organizational characteristics will inhibit the adoption of Unique Device Identification.

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

Unique Device Identification targets critical healthcare processes. Therefore it should be a high priority. The cost of Electronic Health Records, bedside bar coding for pharmaceuticals and data sharing across hospitals and other device user facilities are costs that flow through the hospitals. An integrated system for all of these functions will provide high utility and a low cost point. The marking and identification costs for Unique Device Identification will flow through the device

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manufacturers and suppliers. The tracking costs of UDI will flow through the hospitals. The additional cost of UDI integrated with Electronic Health Records, bedside bar coding for pharmaceuticals and data sharing across hospitals will be marginal.

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 following infrastructure Unique Device Identifier is required:

- Optical scanning devices to read UDI
- Data base for recording inventory of devices in hospital
- Central registration data base for recording UDI/patient data and pedigree information
- Integration of scanning devices to data base
- Inventory data entry capability
- Patient data entry capability
- Human interface to analyze UDI data base for inventory control and recalls

A distinction must be made between the hospitals inventory control system and the UDI/patient Registry. The hospital inventory control system may be part of the Hospital enterprise resource planning (ERP) system. It is expected that a centralized registration data base will be more robust and economically efficient than a localized UDI/patient Registry. Therefore, like the DoD, a central registry will be needed for recall completion purposes.

DoD Medical Treatment Facilities could begin using UDI for equipment management by the end of December 2006. It would require minor modification of our logistics systems to use UDI for inventory management and recall of consumable medical devices. Further, DoD is working towards the identification and recording of equipment and consumables used for a particular patient in his/her electronic health record. UDI would be a significant enabler in this case for retrospective study of product efficacy and patient notification of a product recall.

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?

DoD has a single office that consolidates recall notifications and notifies the MHS of a recall and, in some cases, provides disposal instructions. A recall by UDI would be of benefit for all recalls. This information loaded into our logistics systems would make it simpler to narrow in on and accurately identify the recalled product held in inventory and quickly segregate it for disposal.