

## **How FDA can Empower Medical Device Suppliers to Transform Return Supply Chain with Warranty Expiration and Defective Product Support Under Unique Device Identification (UDI) Mandate and Policies**

**The best way to predict the future is to invent it.**

-- Alan Kay

### **Summary**

Intellareturn has patented novel applications that it would like to further research, customize and pilot for FDA UID enhancement. The core application asks FDA to consider implementation of automated medical device returns with enhanced services by applying passive RFID or Electronic Product Code (EPC) tags for its business case.

The purpose of this application is to set the foundation for future supply change improvements, today. Additionally, it maximizes the take of technology being offered with the applications of RFID being mandated by DoD and others to redefine and stay ahead of the curve.

It is recommended the proposed UID solution be mandated as part of FDA requirements for all medical devices and their core replacement parts, with manufacturers supplying UID data in the RFID tag (placed on both product itself and/or its packaging carton) with required information ready to read by RFID and supplemental barcode reader or manual secure a Web site entry, maintained by Intellareturn Corp., or authorized partners.

This RFID application provides better data and return processing under warranty terms. The RFID tags are linked by Intellareturn Return Server linked directly to medical device warranty rules, purchase expiration dates and return provisions—provided within FDA specified requirements. It is envisioned *the proposed new application will link to UID systems as the data key and result in less paperwork and help to address reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting*. The proposed solution represents a maintenance and safety application that for the first time can provide high-resolution safety returns of defective items and devices.

The proposed UID enhancements with RFID are meant to take advantage of the patented Intellareturn systems and methods that can be linked to UID devices shipped by courier services to support and track medical devices. In particular, it should be noted that DHL has announced formal plans add RFID Tags and related UID (in the form of EPC or other coded UID tag) for every package, product or part it ships. The goal: gain tighter control of shipments, cut costs, and improve operating performance by reducing paperwork and data collection and automating the reverse-logistics processes tied to improving warranty, repairs on defective products. *InformationWeek* (June 10, 2005) reported:

“DHL International GmbH this month starts developing a global IT infrastructure that will let it affix a radio-frequency identification tag on every package it ships by 2015. The goal: gain tighter control of shipments, cut costs, and improve operating performance by reducing paperwork and data collection. DHL's plan to tag every package it handles is a lofty one since the transportation and logistics arm of Deutsche Post World Net ships more than a billion packages a year.”

## Overview

For years, logistics and supply chain management have become leading topics among FDA divisions searching for ways to both predict and optimize their costs of business. As the challenges of the war fighter supply efforts take on increased importance, improving operational performance and efficiency has become a top-level priority.

Over recent months, FDA and commercial companies have bought-into the benefits posed by radio-frequency identification – commonly known as RFID. This technology has existed for years and has grown in acceptance by retail, supply chain and government organizations. Initiatives in RFID are surfacing everywhere. Research leaders predict that safety measures will also prove to be beneficiaries of these RFID efforts. However, some visionaries see it forging a closer affiliation between FDA, companies and the valuable customers they interact with. While this is a great advancement for improving the operational efficiencies of the FDA, much more can be done to enhance services that actually improve efficiencies and reduce costs. But, how can this be achieved?

One way is by incorporating RFID technology into the warranty; ‘lost-and-found’ returns process and reverse logistics facets of medical device product registration and ownership.

### The Solution: RFID Technologies That Provide Value

A medical device manufacturer/supplier would have warranty registration tied into the UID tag on the product or part as part of the vendor and FDA regulation requirements. If the product was lost in shipment or otherwise, it could be identified by its tag and returned via one of the major parcel carriers. If the product needed to be repaired, the customer could go online, enter information at company’s website and a UID would help confirm and authorize return and returns reporting to include the arranging of an automated pick up by an approved courier service (i.e., DHL, FedEx). Simplicity.

The logistics unit doesn't need to fill out a shipping label. When the driver or truck arrives, they scan the tag and use the UID number to retrieve all the information he needs from the Intellareturn Smart Return Service database.

Intellareturn RFID-based Return UID systems are built on the planned operational infrastructure of compatible FDA UID standards by adding data linkage features to create a global, real-time medical device registration, tracking & product return solution.

## I. Company Information

### About Intellareturn Corp.

Intellareturn – a private, New York-based early stage company – provides RFID smart label applications that leverage product registration, return shipping and warranty service touch-points aimed at optimizing the current supplier and customer relationship technologies of their SCM, safety and regulatory enhancements. Essentially, Intellareturn links advanced ID technologies for powerful new logistics applications. The Intellareturn

**Docket: 2006N-0292 - Unique Device Identification; Request for Comments- Submitted by Elliot Klein, Intellareturn Corp., New York, NY <http://www.intellareturn.com>**

Smart Return Service can integrate with existing medical device legacy-shipping solutions, as a technology-agnostic approach to enhancing customer support and FDA regulatory and device safety infrastructure.

Intellareturn provides return technology solutions to securely identify and return virtually any object. Our wireless shipping and notification systems create real-time interaction between products and parcel shipping networks using special labels to automate identification and trigger the return of any item.

Intellareturn creates one seamless return supply chain network, where products or product packaging carton they include, are affixed with labels that can wirelessly transmit their identification to the Internet through radio frequencies. Real-time interaction between products and logistics networks via the Internet or local area network (LAN) help reduce expense in lost, stolen, wasted or delayed product returns and make quantum improvements in the overall efficiency and collaborative abilities of supply chain management.

Intellareturn enables business or consumers with a Return ID Stamp® label or tag to securely, conveniently, and cost effectively returns a product with new speed, convenience and protection benefits. This is especially effective for ‘lost & found’ systems and methods. For Lost & Found application, the core benefit of our system and method serves as a registration incentive to register a new medical device warranty. The “finder” of a missing item with a Return ID Stamp® is encouraged to contact a designated location (i.e., UID for item pickup or return processing). This application reduces the estimated 5% of medical products lost in shipment. It also helps to safeguard the security of radioactive device products and parts that cannot be lost.

Intellareturn enables low-cost automated methods for returns—in essence, building the basic UID communications protocols of the Internet directly onto low-cost labels. Currently, we are focusing on passive tags but are in discussion with some new vendors who have innovative, low-cost active tags. That means that just about anything—from a shipping box, repair part, or a portable medical device—can have the embedded ability to securely send and receive identification data over the Net. Combined with wireless technology, Net-ready chips create Radio Frequency ID (RFID) labels—small inexpensive labels that can live on virtually any manufactured product, spare part or packaging carton to automate the post-sale returns process.

Our network can build on or integrate with the existing operational infrastructure of express parcel carrier and UID networks to create a global, real-time product registration and product return solution. Logistics firms, and their customers, benefit from the Intellareturn infrastructure and technology investments linking its Web-enabled applications to UID legacy return systems.

Labels are wirelessly read at designated physical locations or through the medical device related parcel and logistic service networks. This system triggers automated pick-up and return process notification, payment and tracking. Importantly, our systems can provide

return functionality through printed ID numbers or supplemental bar codes, whenever a radio frequency reader is not available at a location. The combined solution also enables reporting to FDA so if a high number of returns is being processed, the FDA can be alerted with early reporting of a likelihood of a defective medical device. This may be very useful for prompt recall or other FDA repair/service directive.

The Intellareturn automated courier pick up technology and returns network serves as a springboard for future forward and reverse logistics products and services. For example, new services and cost-saving applications to the FDA drug safety programs are anticipated by application of Intellareturn systems and methods.

Intellareturn markets Intellareturn branded ID systems to lead with "intelligent returns," essentially creating a secure return and identification system ON-A-CHIP—where objects can securely share vital information about themselves to special readers. Our system can link to EPCglobal data as demonstrated to EPCglobal and VeriSign in 2005 as a winning finalist in the first EPC/VeriSign Global Developer Software Competition.

Each Return ID Stamp label connects to a database with comprehensive information about the object, including owner name, address information along with other data specific to customer needs. Such additional information can include the contemplated UID data for medical devices and parts, plus additional data requirement coding that link back to the Intellareturn Smart Server to facilitate, repair or service part number, product purchase date, related expiration date, return shipping or FDA safety instructions, or the serial number and ownership data for a portable medical device or other product that needs return service under warranty or defective device return.

## **II. Past Performance Information**

Our service platform is tested with FedEx and now market-ready following five years of market development and testing. At this time, we have full flexibility to establish strategic alliances and market plans with any logistics carrier(s) or parties required to participate in the FDA's proposed UID mandate or other requirements. While we have developed our own software systems, reader and RFID labels, we can also work to complement any bar code or RFID label manufacturer, RFID frequency standard or reader technology. We are a small company with the expertise and Intellectual Property to have the flexibility to integrate with other courier shipping logistics leaders into the UID initiatives using medical device worldwide shipping and reverse-logistics systems. We can represent a stand-alone solution or the next level of electronic return safety label automation for FDA and medical device supplier firms under new UID requirements.

Our novel solution is patented in the United States Patents No. 6,259,367 and 6,965,866. We are actively discussing our solution platform with leading courier networks interested in a pilot for an efficient reverse logistics application using our proprietary systems and methods.

### III. Rough Estimate of Cost and Schedule

It is estimated a prototype system and application can be demonstrated within a 6 to 12 month period at a cost range of \$150,000 to \$450,000. The range depends upon software requirements and UID standards to be issued, that can include the product ownership registration, warranty, repair, and return logistics services described in these comments.

### IV. Major Risks

The major risk is the requirement to finalize FDA's UID standards and co-development plan with Intellareturn and RFID-enabled shippers (or combined RFID with back-up barcode and manual entry of UID numbers) who have proven experience with existing FDA shipping and safety requirements and proven barcode and RFID expertise.

### V. Other Information

Intellareturn has identified partners to participate in a pilot that involve collaboration with FDA, medical device community and outside database partners for the reverse logistics tied to UID-compliant EPC or RFID standards. More importantly, Intellareturn and its potential partners can enhance services for all device and supply chain partners as a result of the RFID and UID technology benefits and recommended warranty, purchase date, ownership data record mandate. The aim is to learn what processes can be applied in based on FDA guidelines, and use the pilot to help evaluate future roll-out programs that save time, money and add efficiencies to reverse logistics tied to warranty related return, safety and automated 'lost & found' asset tagging services. *Such tagging can even provide a new solution for tracking assets within a hospital or medical facility, including inventory management and other post-sale service and repair requirements.*

We see a potential pilot during 2007 for our passive tag application for reverse logistics. This would be tied to UID Return Service or embedded into products themselves (i.e., product EPC 'license plate' tags or special small ID labels on physical corrugated package with instruction to use UID tag data for any warranty, purchase expiration date or related safety, tracking or related FDA reporting or product return event.

We believe our proposed mandated solutions will prove the benefits Intellareturn brings to FDA and patient safety that can lead to reduced expense and better logistics and safety support in reporting and managing of defective medical devices and related products under FDA Unique Device Identification initiatives.

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