5.0 510(k) Summary

Submitted by:	IntelliDOT Corporation 13520 Evening Creek Drive North San Diego, CA 92128
Contact:	David D. Swenson 858-746-3100
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Product:	IntelliDOT Blood Product Administration System
Trade Name	IntelliDOT BPA
FDA Classification:	MMH: software, blood bank, stand alone products
Predicate Device:	BloodTrack V 4.1 BK060041 Neoteric Technology Ltd.

Device Description:

The IntelliDOT Blood Product Administration System, or IntelliDOT BPA, is a transfusion safety management system. IntelliDOT BPA is a module of the IntelliDOT CAREt™ System which is an advanced, wireless workflow optimization and patient safety solution for acute care hospitals and other healthcare providers. IntelliDOT's CAREt™ System operates over a hospital's existing wireless network and is composed of a software application, wireless handheld computing devices and an enterprise-class server and identical back-up server. There is also a test server as a part of the system that is used for in-hospital training. Users may log onto the system from wireless handheld devices to perform bedside safety checks or from their desktop computers to perform administration tasks and view reports.

The CAREt System interfaces to the Hospital Information System, or HIS, and is designed to receive patient admission, discharge and transfer information real-time using standard health industry interface formats. The CAREt System also interfaces to Laboratory Information Systems, or LIS, to receive specimen collection orders such as phlebotomy. Information captured on the CAREt System can be flexibly configured for transmission back to the hospitals computer systems for inclusion in electronic medical record systems or billing systems. Reports can be printed to be included in paper medical records.

IntelliDOT BPA is one of five modules that comprise The CAREt System. The anchor application is the bedside medication administration module, or IntelliDOT BMA, which may be used in conjunction with IntelliDOT BPA and the phlebotomy specimen collection module, or IntelliDOT PSC. Other modules include vital signs collection and mother-baby breast milk matching. All of these applications use the CAREt Handheld device, Model MT 150.

The CAREt Handheld and software application complement the way nurses work, providing a straightforward user interface that supports a fully integrated approach to blood transfusion safety and documentation at the patient's bedside. The CAREt Handheld has two integrated barcode scanners and can read both one dimensional and two dimensional barcodes.

A key way that the CAREt System simplifies nurses work flows is IntelliDOT's Documentation of Treatment or "DOT" system. The DOT System is used to document predetermined clinical documentation choices. In the DOT System, users scan a set of predefined two dimensional symbols called DOTs to initiate workflows such as begin or end transfusion. System managers in a hospital can also create sets of discrete documentation phrases or words with each represented by a unique DOT.

In the IntelliDOT PSC module, the CAREt Handheld is used to match the barcodes on patient wristbands to blood specimen orders received from the LIS. Following specimen collection, bar-coded specimen labels are wirelessly printed at bedside and the labels are adhered to the specimen collection tubes. The IntelliDOT System Server communicates with the wireless printer and establishes a link between the barcodes on patient wristbands to the barcode on the blood specimen label.

The IntelliDOT BPA module links barcodes on the specimen labels to the label barcodes on specific units of blood and then links blood products back to the barcodes on patient wristbands. This process begins with the type and cross match testing performed by blood bank personnel according to hospital's standard policies. The CAREt Handheld guides the user to perform the tasks necessary to assign specific units of blood products to patients. Once a unit of blood is assigned to a patient, the IntelliDOT BPA prints a Blood Product Issue Tag which includes unique DOTs that contain the patient identification information that is on the patient's wristband as well as information from the label on the assigned unit. These Blood Product Issue Tags are attached to the assigned unit. The DOTs printed on Blood Product Issue Tags are used to guide the nurse at the bedside through steps to verify that a patient receives the correct unit of blood.

When using the IntelliDOT BPA module, nurses receive alerts and reminders on the CAREt Handheld display specific for their patients needing blood, including real-time information on blood transfusion suitability and reminders to check the transfusing patient's condition and complete predefined documentation and transfusion related tasks. By simply scanning a DOT to enter the blood administration workflows, the CAREt Handheld guides the nurse through all required documentation tasks to safely administer blood. At bedside the CAREt Handheld guides the nurse through predefined documentation tasks that have accumulated for that patient.

The CAREt System includes a report printing function which allows system mangers to configure and print reports on all system functions, including blood transfusion safety management and caregiver compliance to hospital documentation policies. Reports may be printed ad-hoc, or may be scheduled to repeat on a regular basis. Blood transfusion records are designed to become a permanent part of the patient's medical record, in either a hard copy printed or electronic format.

Intended Use:

The IntelliDOT Blood Product Administration (IntelliDOT BPA) is a point-of-care Transfusion Safety Management System composed of computers, a software application, wireless handheld barcode scanners and wireless printers. IntelliDOT BPA is intended to assist in positive patient identification for the transfusion of blood products. The system assists phlebotomists with correct labeling of specimen collection tubes at the patient's bedside, assists laboratory personnel in accurate matching of blood samples with correct blood products, and assists nurses in transfusing blood products to the correct patient. IntelliDOT BPA is intended to increase transfusion safety and is intended for use by healthcare professionals trained in the administration of blood transfusions.

In addition to the features of the IntelliDOT BPA, the predicate device can track blood and blood products at the storage location. This is not a feature of IntelliDOT BPA.

This software should not be used as the sole method for determining transfusion safety. This software is meant as a clinical aid and requires use by trained professional personnel.

Conclusions from Bench and Clinical Testing:

Tests were performed on the bench and in a clinical setting to evaluate the use of IntelliDOT BPA to provide transfusion safety management. The testing included attempts to assign expired blood products to a patient and none of the expired blood products was assigned to a patient. There were attempts made to transfuse blood to a patient to whom specific blood products were not assigned, and the system accurately warned the caregiver not to proceed with the transfusions.

These evaluations of the IntelliDOT BPA System show that the software and accessories provide accurate blood unit assignments to patients and warns caregivers when blood transfusions are attempted for patients who have not been assigned to specific units of blood or blood products. The IntelliDOT BPA system meets the stated indications for use.

Table 5-1: Technical Characteristic Comparison

Characteristic	IntelliDOT BPA	BloodTrack V4.1
Operating System	Server: Linux Desktop Client: Microsoft Windows XP Pro SP2 Handheld: Microcontroller Linux OS	Server: Microsoft Windows 2000 Server Microsoft Windows Sever 2003 Microsoft Windows XP Professional Kiosk and Desktop client: Microsoft Windows 2000 Pro Microsoft Windows XP Pro Handheld client: Microsoft Windows Pocket PC Microsoft Windows Mobile
Database	PostgreSQL Database	Microsoft SQL Server 2000
System Server:	Xeon 3000 CPU, 3.2Ghz, 2MB cache, 800FSB (Single CPU) 2GB RAM, RAID 5 Disk Configuration, 4 x 73GB Disk Space, CD-ROM drive, 2 x 1Gb Network Interface Card, Non-Redundant Power Supply	Minimum Pentium Class CPU, 600 MHz, 40 GB hard drive, 512 MB RAM, 10/100 Base-T Ethernet Adapter
Desktop System Manager:	Pentium 4 CPU, 2.8Ghz 504Mb Ram, 10Mb available disk space, 10/100 Base-T Ethernet Adapter or 802.11 b WiFi Adapter, Color Monitor with 800 x 600 resolution	Minimum Pentium Class CPU, 600 MHz, 40 GB hard drive. 512 MB RAM, 101100 Base-T Ethernet Adapter, 15" Color Monitor
Printer:	Xerox 7655 PS, HP 5000N, HP LaserJet 4Plus or HP LaserJet 2420	Windows Compatible Printer
Handheld client:	CAREt Handheld MT 150	Symbol MC 70 PDA with scanner capable of reading 2D barcodes.
Specimen Label Printer:	OC2 Label Printer Model 200326-100 O'Neil Product Development, Inc.	QL 220 Label Printer Zebra Technologies Corp.
Application Language	JAVA Virtual Machine	C++
Interface	TCP/IP socket interface, HL7 message format.	TCP/IP socket interface, proprietary message format.