6.0 510(k) Summary

6.1 General

Name and Address of Manufacturer

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Date Summary Prepared

July 13, 2006

Product Name

BloodTrack V4.1

Product Code

81MMH

Device Classification

Not classified

Performance Standards

There are no FDA performance standards promulgated for this device.

6.2 Substantial Equivalence Claim

BloodTrack V4.1 is substantially equivalent to BloodTrack Courier V3.2 manufactured by Neoteric Technology Limited, BloodTrack SafeTx V2.0 manufactured by Neoteric Technology Limited and Misys Laboratory™, Blood Bank and Donor, V6.0.1 manufactured by Misys Healthcare Systems.

BK050059 was submitted for BloodTrack Courier V3.2 and was cleared for commercial distribution in December 2005.

BK050032 was submitted for BloodTrack SafeTx V2.0 and was cleared for commercial distribution in August 2005.

BK040065 was submitted for Misys Laboratory, Blood Bank and Donor, V6.0.1 and was cleared for commercial distribution in October 2004.

6.3 Device Description

BloodTrack is a modular electronic information management system built on a three-tier client/server architecture consisting of four separate software client applications interfaced with server based business services and database layers. Three of the four client software applications have clinical applications. These are:

- BloodTrack Manager V4.1
- BloodTrack Courier V4.1
- BloodTrack SafeTx V2.1

The fourth client software application is Neoteric ASK Manager, an administrative utility that can be used by authorized system administrators to create and manage user accounts for the caregivers that use the BloodTrack system. A description of each of the three software clients with clinical applications is provided below.

6.3.1 BloodTrack Manager

BloodTrack Manager V4.1 is a software client application used by trained healthcare professionals to help prevent latent errors by monitoring the handling, transportation and transfusion of blood or blood products by means of:

- Monitoring the status of all locations where blood units are stored and BloodTrack Courier is deployed.
- Reporting and resolution of system alerts that occur during the movement and transfusion of blood units.
- Recording the movement of blood units in or out of storage locations within the Blood Bank.
- Reporting of blood unit movements, inventory lists, expiry and transaction histories, and transfusion history.
- Creating and maintaining an audit trail of each movement of the blood unit into and out of the storage location that can be displayed and reviewed.
- Activation of blood units for management under BloodTrack where there is no BECS interface.
- Recording the arrival of a blood unit and final disposition of a blood unit.

- Determining whether blood is available for a patient.
- Printing a pickup slip used to retrieve blood units from a storage location.
- Monitoring the status of active blood transfusions.

BloodTrack Manager has been validated on the Hewlett Packard Compaq model d220 MT personal computer.

6.3.2 BloodTrack Courier

BloodTrack Courier V4.1 is a software client application used by trained healthcare professionals to help prevent latent errors by monitoring the handling, transportation and transfusion of blood or blood products by means of:

- Controlling access to blood units at managed storage locations.
- Recording the movement of blood units in or out of managed storage locations
- Monitoring the length of time that a blood unit remains outside of refrigeration and warning the user if the blood unit has been out of the refrigerator for an unacceptable length of time.
- Verifying the expiry date of a blood unit and warning the user if the expiry date has passed.
- Verifying the dereservation date for a blood unit and warning the user if the dereservation date has passed.
- Verifying a complete audit trail for a blood unit and warning the user if the audit trail is not complete
- Reducing the risk of a caregiver picking up the wrong blood unit for a patient by requiring confirmation of the patient's identification when blood units are removed from a storage location to be delivered to the patient's bedside.
- Warning users if a blood unit with an expiry date older than the expiry date of the blood unit just removed is still available at the storage location.
- Allowing for Remote Release, a process where a compatibility label is remotely printed and applied to a blood unit outside of the Blood Bank. Remote Release involves the use of an inventory of unassigned blood units maintained in BloodTrack managed storage locations outside of the Blood Bank. When blood is needed for a patient, BloodTrack verifies the patient's eligibility for Remote Release by querying the Blood Establishment Computer System (BECS) and if eligible, prints a compatibility label to be applied to the blood unit at the managed storage location. Although the compatibility label may be printed remotely by BloodTrack, the decision to print the compatibility label is still made by the BECS. In simple terms, the BloodTrack Remote Release process simply changes the location where the compatibility label is printed and applied to the blood unit.
- Recording the final disposition of a blood unit.

BloodTrack Courier has been validated on a custom made computer kiosk, manufactured by GBE Electronics of Lancing UK, equipped with a touch-screen panel, barcode scanner, and connected to a Zebra TLP2824 printer,. The kiosk is mounted on the wall next to a blood storage location, or integrated into a storage location cabinet. The kiosk controls access to the storage location via an electromagnetic lock.

6.3.3 BloodTrack SafeTx

BloodTrack SafeTx V2.1 is a software client application used by trained healthcare professionals to help prevent latent errors by monitoring the handling, transportation and transfusion of blood or blood products by means of:

- Providing positive patient identification at the bedside when blood samples are collected and at the time of transfusion of blood or blood products
- Reducing the risk of a caregiver picking up the wrong blood unit for a patient by printing a pickup slip at the bedside.
- Prompting the user at each stage of the transfusion process to scan patient identification, blood unit or compatibility barcode labels, enter patient vital signs, confirm special blood requirements, record volume transfused or indicate transfusion reactions
- Creating a record of the transfusion that may be printed for the patient's record, stored and uploaded to a database.

BloodTrack SafeTx has been validated on the Symbol MC70 handheld personal digital assistant (PDA) devices equipped with a barcode scanner and connected to a Zebra QL 220 mobile printer.

6.4 Intended Use of the Device

BloodTrack is an electronic information management system intended for use in healthcare facilities by trained healthcare professionals to help prevent latent errors by monitoring the handling, transportation and transfusion of blood or blood products so that complete audit trails are recorded.

BloodTrack can enhance transfusion safety by providing for positive patient identification at the bedside when blood samples are collected and at the time of transfusion of blood or blood products.

BloodTrack can also reduce the risk of a healthcare professional retrieving the wrong blood unit for a patient by printing a blood product pickup slip at the bedside and requiring confirmation of the patient's identification when blood units are removed from a managed storage location to be delivered to the patient's bedside. Each time a blood unit is removed from, or placed into a managed storage location, BloodTrack verifies the expiration date of the blood unit, that the audit trail for the blood unit is complete, and that the blood unit has not been out of refrigeration too long. If the blood unit has expired, the audit trail is incomplete or the blood unit has been out of refrigeration too long, BloodTrack warns the user of the problem.

BloodTrack can control remote release, a process where a compatibility label is remotely printed and applied to a blood unit outside of the Blood Bank. Remote Release involves the use of an inventory of unassigned blood units maintained in BloodTrack managed storage locations outside of the Blood Bank. When blood is needed for a patient, BloodTrack verifies the patient's eligibility for Remote Release by querying the Blood Establishment Computer System (BECS) and if eligible, prints a compatibility label to be applied to the blood unit at the managed storage location. Although the compatibility label may be printed remotely by BloodTrack, the decision to print the compatibility label is still made by the BECS. In simple terms, the BloodTrack Remote Release process simply changes the location where the compatibility label is printed and applied to the blood unit.

BloodTrack can prompt the user at each stage of the transfusion process to scan patient identification, blood unit or compatibility barcode labels, enter patient vital signs, confirm special blood requirements, record volume transfused or indicate transfusion reactions. BloodTrack creates a record of the transfusion that may be printed for the patient's record, stored and uploaded to a remote database.

BloodTrack maintains an audit trail of each movement of the blood unit, from activation in the BloodTrack system through to final disposition, which can be remotely stored, displayed monitored, and printed.

6.5 Identification of Predicate Devices

Manufacturer	Neoteric Technology Ltd	Neoteric Technology Ltd	Misys Healthcare Systems
Common Name	BECS	BECS	BECS
Trade Name	BloodTrack Courier V3.2	BloodTrack SafeTx V2.0	Misys Laboratory™, Blood Bank and Donor, V6.0.1
Reference Number assigned by FDA	BK050059	BK050032	BK040065

6.6 Comparison to Predicate Devices: Intended Use

BloodTrack V4.1	**BloodTrack Courier V3.2** (from 510(k) summary)	**BloodTrack SafeTx V2.0** (from 510(k) summary)	**Misys Laboratory™, Blood Bank and Donor, V6.0.1** (from 510(k) summary)
BloodTrack is an electronic information management system intended for use in healthcare facilities by trained healthcare professionals to help prevent latent errors by monitoring the handling, transportation and transfusion of blood or blood products so that complete audit trails are recorded. BloodTrack can enhance transfusion safety by providing for positive patient identification at the bedside when blood samples are collected and at the time of transfusion of blood or blood products. BloodTrack can also reduce the risk of a healthcare professional retrieving the wrong blood unit for a patient by printing a blood product pickup slip at the bedside and requiring confirmation of the patient's identification when blood units are removed from a managed storage location to be delivered to the patient's bedside. Each time a blood unit is removed from, or placed into a managed storage location, BloodTrack verifies the expiration date of the blood unit, that the audit trail for the blood unit is complete, and that the blood unit has not been out of refrigeration too long. If the blood unit has expired, the audit trail is incomplete or the blood unit has been out of refrigeration too long, BloodTrack warns the user of the problem. BloodTrack can control Remote Release, where an inventory of unassigned blood units is maintained in managed storage locations outside of the Blood Bank. When blood is	BloodTrack Courier is intended for use in hospitals by trained healthcare professionals having the authority to move blood units from place to place in the hospital. BloodTrack Courier is intended to increase transfusion safety by monitoring the length of time that a blood unit remains outside of refrigeration and warning the user if the blood unit has been out of the refrigerator for an unacceptable length of time. BloodTrack Courier can also reduce the risk of a caregiver picking up the wrong blood unit for a patient by requiring confirmation of the patient's identification when blood units are removed from a refrigerator to be delivered to the patient's bedside. Each time a blood unit is removed from, or placed into a storage refrigerator, BloodTrack Courier verifies the expiration date of the blood unit, that the audit trail for the blood unit is complete, and that the blood unit has not been out of refrigeration too long. If the blood unit has expired, the audit trail is incomplete or the blood unit has been out of refrigeration too long, BloodTrack Courier warns the user of the problem. BloodTrack Courier creates and maintains an audit trail of each movement of the blood unit into and out of the refrigerator that can be displayed and reviewed.	BloodTrack SafeTx is intended to be used in the hospital by trained healthcare professionals to increase transfusion safety by providing positive patient identification at the bedside when blood samples are collected and at the time of transfusion of blood and blood products. At each stage of the process, the caregiver is given prompts by the BloodTrack SafeTx requiring then to enter patient vital signs, confirm special blood requirements, record volume transfused or indicate transfusion reactions. Each response is recorded in a transfusion record and can be printed for the patient's record.	The Blood Bank and Blood Donor system is intended for use by trained healthcare professionals responsible for donor and transfusion services in the following ways: • Display data that assists healthcare professionals make decisions regarding the suitability of donors • Generate deferrals to the donor record and maintain donor records • Maintain phlebotomy records • Store records of manufactured and blood product component preparation • **Record the released of manufactured and blood products for infusion** • **Maintain manufactured and blood product inventory including the tracking of autologous and directed blood products** • **Maintain a historical record of the patient's blood bank and transfusion related data** • Record testing results of patient specimens and blood products either manually or through instrument interfaces • **Maintain a product history from time received until final disposition** • Display data required to assist healthcare professionals when

BloodTrack V4.1	**BloodTrack Courier V3.2** (from 510(k) summary)	**BloodTrack SafeTx V2.0** (from 510(k) summary)	**Misys Laboratory™, Blood Bank and Donor, V6.0.1** (from 510(k) summary)
needed for a patient, BloodTrack verifies the patient's eligibility for Electronic Cross-Matching as determined by the Blood Establishment Computer System and if eligible, prints a compatibility label to be applied to the blood unit at the managed storage location. BloodTrack can prompt the user at each stage of the transfusion process to scan patient identification, blood unit or compatibility barcode labels, enter patient vital signs, confirm special blood requirements, record volume transfused or indicate transfusion reactions. BloodTrack creates a record of the transfusion that may be printed for the patient's record, stored and uploaded to a remote database. BloodTrack maintains an audit trail of each movement of the blood unit, from activation in the BloodTrack system through to final disposition, which can be remotely stored, displayed monitored, and printed.			qualifying patients for electronic crossmatch • Perform quality assurance checks and maintain assurance records.

6.7 Comparison to Predicate Devices: Features

Feature	BloodTrack V4.1	BloodTrack Courier V3.2	BloodTrack SafeTx V2.0	Misys Laboratory ™, Blood Bank and Donor, V6.0.1
System Access Security	Authorized users are assigned an electronically readable and unique identification code that must be entered and validated before access to the system is allowed. Users are only provided access to modules and functions based on rights that have been assigned by system administrators. System times-out after period of inactivity.	Authorized users are assigned an electronically readable and unique identification code that must be entered and validated before system access is allowed. Users are only provided access to functions based on rights that have been assigned by system administrators. System times-out after period of inactivity.	Authorized users are assigned an electronically readable and unique identification code that must be entered and validated before system access is allowed. System times-out after period of inactivity.	Manages user ID and password combinations. Manages access to system across and within facilities. Maintains login histories.
Patient Identification Verification	Patients are assigned an electronically readable and unique identification code that includes patient's identity number, last name, first name, date of birth and sex that is encoded in a linear or two-dimensional (2D) barcode printed on a patient wristband. Users are prompted to enter patient identification for confirmation by the system at the appropriate stages of the process. If the patient identification is incorrect the system warns the user of the problem.	Patients are assigned an electronically readable and unique identification code that includes patient's identity number, last name, first name, date of birth and sex that is encoded in a linear or 2D barcode printed on a patient wristband. Users are prompted to enter patient identification for confirmation by the system at the appropriate stages of the process. If the patient identification is incorrect the system warns the user of the problem.	Patients are assigned an electronically readable and unique identification code that includes patient's identity number, last name, first name, date of birth and sex that is encoded in a linear or 2D barcode printed on a patient wristband. Users are prompted to enter patient identification for confirmation by the system at the appropriate stages of the process. If the patient identification is incorrect the system warns the user of the problem.	(Not a feature)
Blood Sample Collection and Labeling	Users are prompted to enter patient identification by scanning the wristband, tests are selected, and a sample label(s) is printed to a mobile printer.	(Not a feature)	Users are prompted to enter patient identification by scanning the wristband, tests are selected, and a sample label(s) is printed to a mobile printer.	(Not a feature)
Blood Unit Storage Location Management	Computer kiosks are installed at blood unit storage locations. The system controls the refrigerator door	Computer kiosks are installed at blood unit storage locations. The system controls the refrigerator door	(Not a feature)	The Blood Bank application includes the following capabilities: • **Inventory control**

Feature	BloodTrack V4.1	BloodTrack Courier V3.2	BloodTrack SafeTx V2.0	Misys Laboratory ™, Blood Bank and Donor, V6.0.1
	locks. Users must open the refrigerator by logging into system. Each time a blood unit is removed from, or placed into a managed storage location, BloodTrack verifies the expiration date of the blood unit, that the audit trail for the blood unit is complete, and that the blood unit has not been out of refrigeration too long. If the blood unit has expired, the audit trail is incomplete or the blood unit has been out of refrigeration too long, BloodTrack warns the user of the problem.	locks. Users must open the refrigerator by logging into system. Each time a blood unit is removed from, or placed into a managed storage location, BloodTrack verifies the expiration date of the blood unit, that the audit trail for the blood unit is complete, and that the blood unit has not been out of refrigeration too long. If the blood unit has expired, the audit trail is incomplete or the blood unit has been out of refrigeration too long, BloodTrack warns the user of the problem.		• Patient History • **Autologous/direct unit tracking** • Patient testing • Patient and product testing transmitted form blood bank analyzers • Component preparation • Electronic crossmatching • Product dispensing data evaluation • User-defined unit tags • Inquiry.
Blood Unit Pickup	The system requires the user to enter the patient identification and prints a blood product pickup slip at the bedside. The system requires the user to enter patient's identification by scanning the pickup slip when blood units are removed from a managed storage location to be delivered to the patient's bedside. The system verifies a correct match between the patient's identification on the pickup slip and the patient's identification on the blood unit. If there is a mismatch the system warns the user of the problem.	The system requires the user to enter patient's identification by scanning the pickup slip when blood units are removed from a managed storage location to be delivered to the patient's bedside. The system verifies a correct match between the patient's identification on the pickup slip and the patient's identification on the blood unit. If there is a mismatch the system warns the user of the problem.	The system requires the user to enter the patient identification and prints a blood product pickup slip at the bedside.	(Not a Feature)
Compatibilty label printing	When blood is needed for a patient, BloodTrack verifies the patient's eligibility for Electronic Crossmatching as determined by the Blood Establishment Computer System and if eligible, prints a compatibility label to be applied to the blood unit at the managed	(Not a feature)	(Not a feature)	The Blood Bank application includes the following capabilities: • Inventory control • Patient History • Autologous/direct unit tracking • Patient testing

Feature	BloodTrack V4.1	BloodTrack Courier V3.2	BloodTrack SafeTx V2.0	Misys Laboratory ™, Blood Bank and Donor, V6.0.1
	storage location.			• Patient and product testing transmitted form blood bank analyzers • Component preparation • Electronic crossmatching • Product dispensing data evaluation • **User-defined unit tags** • Inquiry.
Blood Unit Transfusion	At each stage of the transfusion process the system prompts the user to scan patient identification, blood unit or compatibility barcode labels, enter patient vital signs, confirm special blood requirements, record volume transfused or indicate transfusion reactions. BloodTrack creates a record of the transfusion that may be printed for the patient's record, stored and uploaded to a remote database.	(not a feature)	At each stage of the transfusion process the system prompts the user to scan patient identification, blood unit or compatibility barcode labels, enter patient vital signs, confirm special blood requirements, record volume transfused or indicate transfusion reactions. BloodTrack creates a record of the transfusion that may be printed for the patient's record, stored and uploaded to a remote database.	Maintain a historical record of the patient's blood bank and transfusion related data. (from Intended use)
Recording and Reporting	The system maintains an audit trail of each movement of the blood unit, from activation in the system through to final disposition. Records can be remotely stored, displayed, monitored, and printed.	The system maintains an audit trail of each movement of the blood unit, from activation in the system. Records can be remotely stored, displayed, monitored, and printed.	The system creates a record of the transfusion that may be printed for the patient's record.	Maintain a product history from time received until final disposition. Perform quality assurance checks and maintain assurance records. (from Intended use)

6.8 Comparison to Predicate Devices: Technical Characteristics

Technical Characteristic	BloodTrack V4.1	BloodTrack Courier V3.2	BloodTrack SafeTx V2.0	Misys Laboratory™, Blood Bank and Donor, V6.0.1
Operating System	**Server** Microsoft Windows 2000 Server Microsoft Windows Server 2003 Microsoft Windows XP Professional **Kiosk and Desktop client:** Microsoft Windows 2000 Professional Microsoft Windows XP Professional **Handheld client:** Microsoft Windows Pocket PC Microsoft Windows Mobile	Microsoft Windows 2000 Professional.	Microsoft Pocket PC 2002 operating system.	Unix IBM AIX (Version 5.1) operating systems (databases and application server) Microsoft Windows 2000 or XP Professional (client processing environment)
Database	Microsoft SQL Server 2000	Microsoft Jet.	(not a characteristic)	InterSystems Cache' post relational database version 4.1.12 and 4.1.16
Hardware	**Server** Minimum Pentium Class CPU, 600 MHz, 40 GB hard drive, 512 MB RAM, 10/100 Base-T Ethernet Adapter **Desktop client:** Minimum Pentium Class CPU, 600 MHz, 40 GB hard drive, 512 MB RAM, 10/100 Base-T Ethernet Adapter, 15" Color Monitor, Windows Compatible Printer **Kiosk** Minimum Pentium Class CPU, 600 MHz, 40 GB hard drive, 256	Pentium processor, 600 MHz, 40 GB hard drive, LCD SVGA Touch-screen, 256 MB RAM, 10/100 megabit Network Interface Card.	Symbol PPT 2846 PDA with scanner capable of reading 2D barcodes.	Operates on general purpose hardware supplied by commercial manufacturers.

Technical Characteristic	BloodTrack V4.1	BloodTrack Courier V3.2	BloodTrack SafeTx V2.0	Misys Laboratory™, Blood Bank and Donor, V6.0.1
	MB RAM, 10/100 Base-T Ethernet Adapter, LCD SVGA touch-screen, imaging barcode scanner capable of reading 2D barcodes. **Handheld client:** Symbol MC 70 PDA with scanner capable of reading 2D barcodes.			
Application Language	C++	Microsoft Visual Basic V6.	C++	Visual Basic, Visual C++, Cache'
Interface	TCP/IP socket interface, proprietary message format.	File transfer or TCP/IP socket interface, proprietary message format.	Does not interface with BECS, LIS, or HIS.	Barcode scanner, keyboard, and interfaces with blood grouping instruments.

6.9 Summary of Clinical and Non-Clinical Testing and the Conclusion

Unit, integration and system level testing were performed by Neoteric in accordance with the defined test plans on the platform identified in the 510(k) submission. Beta testing was performed at a user facility in accordance with the applicable test plan that included scenario testing based on the intended use of the device. Based on the testing, BloodTrack V4.1 appears to be as safe and effective for the intended use as the identified predicate devices.