

6.0 510(k) Summary



6.1 General

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Name and Address of Manufacturer

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Date Summary Prepared

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Product Name:

BloodTrack SafeTx Version 2.0

Product Code:

81MMH

Device Classification:

Not classified

Performance Standards:

There are no FDA performance standards promulgated for this device—however the *Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software*, January 13, 1997, was utilized as a special control.

6.2 Substantial Equivalence Claim

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BloodTrack SafeTx Version 2.0, is substantially equivalent to wBlood Care 1.0, manufactured by Care Fusion, in intended use, features, and technical characteristics. BK040002 was submitted for wBloodCare and was cleared for commercial distribution in 2004.

6.3 Description of the Device

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BloodTrack SafeTx provides transfusion verification by scanning the patient's barcoded hospital identification wristband and blood product barcodes to confirm that the blood product is the one intended for the patient. BloodTrack SafeTx records the start and stop times of transfusions, allows the user to input vital signs, record transfusion reactions, and volume transfused, and allows the user to print transfusion information to a label that may be affixed to the patient's chart. BloodTrack SafeTx is intended to be used only by professionals who have received training on the proper use of this device and performing blood transfusions.

BloodTrack SafeTx uses a handheld PDA device with a graphical user interface. The primary method of user input is through the barcode scanner and the touch screen. Users scan a patient's barcoded hospital identification wristband and print barcoded and eye-readable labels for blood samples and blood product pickup slips.

BloodTrack SafeTx application software is written in C++ and operates on the commercially available Symbol PPT 2846 PDA with the Microsoft Pocket PC 2002, Service Pack 4 operating system. BloodTrack SafeTx interfaces with the Zebra QL220 mobile printer that is used to print labels with two dimensional barcodes and eye-readable text.

6.4 Intended Use of the Device

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BloodTrack SafeTx is intended for use in hospitals by healthcare professionals trained in the administration of blood transfusions. BloodTrack SafeTx is intended 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 or blood products. At each stage of the process, the caregiver is given prompts by BloodTrack SafeTx, requiring them to scan patient, blood unit or compatibility label barcodes, enter patient vital signs, confirm special blood requirements, record volume transfused or indicate transfusion reactions. Each response is recorded in a transfusion record that may be printed for the patient's record.

6.5 Comparison to Predicate Device: Intended Uses

BloodTrack SafeTx	Care Fusion wBlood Care 1.0
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, BloodTrack SafeTx prompts the caregiver to enter patient vital signs, confirm special blood requirements, record volume transfused or indicate transfusion reactions. Each response is recorded in a transfusion record that is stored in the BloodTrack database and can be printed for the patient's record.	wBloodCare is a comprehensive computer software application that manages transfusion service activities. It maintains a transfusion history, tracks patient identification information, captures orders for patient blood product administration(s), tracks product delivery/disposition related to release of product, assists in determination of suitability of blood products, and records transfusion activities and results.

6.6 Comparison to Predicate Device: Features

BloodTrack SafeTx	Care Fusion wBlood Care 1.0 (From Care Fusion web site)
Secure access to application	Secure access to application
Patient identification display provides several qualifiers including patient's first name, last name, hospital identification number, date of birth and gender	Patient identification display provides several qualifiers including name, hospital identifier, date of birth and gender
Does not interface with the hospital or laboratory information system	Display of allergy information provided by hospital information system
Does not interface with the hospital or laboratory information system	View of patient's active transfusion orders
Optional user defined pre-transfusion checklist	Pre-transfusion checklist
Electronic comparison of the barcode of the blood product unit number and product code with the same barcoded information on the compatibility tag affixed to the unit	Electronic match of barcode on blood product unit with unit number assigned by blood bank
Records the date and time a sample is collected, a transfusion is started, and when a transfusion is stopped	Electronic auto collection of start, stop and completion times
Records volume transfused and transfusion reactions	Reaction documentation
Multiple vital sign entries with auto time stamps and identification of the caregiver	Multiple vital sign entries with auto time stamps
View of vital signs history for transfusion episode	View of vital signs history for transfusion episode
Ongoing view of transfusion details history	Ongoing view of transfusion details history
Displays a message to the caregiver when 30 minutes have passed since the blood product arrived at the patient's location and the transfusion has not been started	Hospital defined blood product expiration notifications
Printable transfusion record	Printable transfusion record

6.7 Comparison to Predicate Device: Technical Characteristics

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	BloodTrack SafeTx	Care Fusion wBlood Care 1.0 (From Care Fusion web site)
Operating System	Microsoft Pocket PC 2002 operating system	Microsoft Windows 2000, Pocket PC and CE.net operating systems
Hardware	Symbol PPT 2846 PDA with scanner capable of reading two dimensional barcodes	Symbol PPT 8846 PDA with integrated laser scanner
Application Language	C++	Unknown
Interface	Does not interface with BECS, LIS, or HIS	HL7 based Interface Engine for integration with various healthcare information systems

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

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Unit, integration and system level testing was performed by Neoteric in accordance with the defined test plan on the platform identified in the 510(k) submission and in the *BloodTrack SafeTx Version 2.0 User Guide* located in *Appendix A User Guide* of this 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 clinical and non-clinical testing, BloodTrack SafeTx appears to be as safe and effective as the identified predicate device.