BK980023

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510(k) SUMMARY

A1. Submitted by:

Thomas F. Marcinek, President and Chief Operating Officer
Wyndgate Technologies
11060 White Rock Road, Suite 200
Rancho Cordova, California 95670
Phone: (916) 638-3336, extension 2329
Fax: (916) 638-3214

A2. Device Name:

Common Name:	Transfusion Service Management Information System
Trade/Proprietary Name:	SafeTrace Tx™, Version 1.0
Classification Name:	Stand Alone Blood Bank Software, Product Code 81 MMH.

A3. Substantial Equivalence:

SafeTrace Tx is substantially equivalent in its intended use and features to Cerner PathNet Blood Bank Transfusion software, cleared for commercial distribution under BK950053.

SafeTrace Tx Intended Use	Cerner PathNet Blood Bank Transfusion BK950053 Intended Use
A comprehensive computer software package that manages the information system needs of a transfusion service. Maintains a complete test and transfusion history for a patient and comprehensive tracking of donor products from receipt to final disposition. Helps transfusion services:	Reduce general operational problems associated with laboratory management by: ▪ tracking blood bank products from receipt through final disposition, ▪ recording patient testing data ▪ providing inquiries and reports to access the stored information
Manage an inventory of blood for patients	Product Inventory
Track patient identification information	Admission, Transfer and Discharge (ADT)
Manage patient visits and specimens	ADT and Specimen Collection
Capture orders for patient tests and blood products	Order Entry
Track product disposition	Product Inventory
Assist in the determination of the suitability of released products	Inventory Transactions
Record transfusion results.	Results Entry

Feature	SafeTrace Tx	Cerner PathNet Blood Bank Transfusion BK950053
Functional Overview	Tracks blood bank products from receipt to final disposition, from entering products into inventory through modifying, pooling, crossmatching, issuing, transfusing to a patient, returning, and shipping to another institution or back to the supplier.	Tracks blood bank products from receipt to final disposition, from entering products into inventory through modifying, pooling, crossmatching, dispensing, transfusing to a patient, returning, and shipping to another institution or back to the supplier.
Inventory	Contains the major functions needed to receive, transfer, and ship products, review and update product records, and link products with recipients, manage and reconcile product inventory.	Provides the functionality needed to receive products, enter results, modify or pool products, dispense products, make inquiries on products, and generate blood bank reports.
Patient/Order	Contains the major functions that manage the registration of a patient, maintain patient records, and manage specimens, help manage placement and tracking of orders, entry and interpretation of patient and product test results, the selection, allocation, processing and testing of products, including crossmatch, component modification, component pooling, component division, product issue and product return.	Provides the functionality needed: for the entry and inquiry of patient demographic information; for the entry and inquiry of patient and product orders; to inquire on patient results and laboratory-type procedures and maintain entered quality control data; for the entry and inquiry of patient and product orders; to generate patient charts (reports) containing user-defined procedures and formats; and to schedule and print orders on specimen collection lists and labels.
Table Administration	Allows user with security authorization to add, update, or outdate data. Provides functionality to build user-defined	Provides the functionality for building user-definable reference tables and databases.

Feature	SafeTrace Tx	Cerner PathNet Blood Bank Transfusion BK950053
	tables. Provides hard-copy listing of each table and its contents. Contains administrative functions for the maintenance of tests, products, services and providers.	
Security	Maintains user ID and password combinations. Manages access to system. Maintains login histories. Repository for all user security profiles across all facilities.	Maintains user ID and password combinations. Manages access to system. Institution may implement additional security features.
Audit Functionality	Audits data changes. Review audit records.	Monitors system performance and function. The Transaction Logging (TL) file maintains a database of transactions (updates) to key files.
Report Generation	Provides a standard set of reports.	Provides the functionality to generate blood bank reports and to generate patient charts (reports) containing user-defined procedures and formats.

The software functionality of the SafeTrace TX application is substantially equivalent to the Cerner PathNet application.

SafeTrace TX OS/Database/Hardware Environment	Cerner PathNet OS/Database/Hardware Environment
Application Server operates on Microsoft Windows NT Server Version 3.51 or higher.	Cerner PathNet operates on standard Digital Equipment Corporation (DEC) and IBM Unix Hardware and Operating Systems.
Database Server operates on Oracle Relational Database Management System version 7.3 or higher and Oracle SQLNET 2 or higher.	Cerner PathNet operates on person-centric relational database.
Client Processing Environment with Microsoft Windows 95 or higher or Windows NT Version 3.51 or higher, and Oracle SQLNET 2 or higher.	Cerner PathNet client side user interface is through Microsoft Window 95 or Windows NT or terminals.

The operating system, database and hardware characteristics of the SafeTrace TX application are different but substantially equivalent to the Cerner PathNet application.

SafeTrace Tx Other Technological Characteristics	Cerner PathNet Other Technological Characteristics
Application Language - Inprise Delphi	Application Language – COBOL, C, CCL
Database – Oracle Relational Database Management System	Database – Person-centric relational database
User Interface – Windows 95 and Windows NT	User Interface – Windows 95,Windows NT and terminals
Architecture – Highly scaleable, multi-tier client server	Architecture – Highly scaleable, multi-tier client server
Platforms – Open industry standard	Platforms – Open industry standard

SafeTrace TX Life Cycle Characteristics	Cerner PathNet Life Cycle Characteristics
Project Feasibility	
Requirements	Specification/Requirements
Design	Design
Development	Implementation
Documentation	
Training	
System Test	Verification & Validation – System Test
Beta Test	Verification & Validation – Alpha Test
Maintenance	Maintenance
Configuration Management Document Control	Revision Control

The other technological and life cycle characteristics of SafeTrace Tx and Cerner PathNet are substantially equivalent.

A4. Device Description:

Overview

SafeTrace Tx is a comprehensive software package that helps manage the information system needs of a transfusion service. SafeTrace Tx is designed to help meet the needs of both centralized and standalone transfusion services.

SafeTrace Tx maintains a complete test and transfusion history for a patient and tracks donor products from receipt to final disposition. Each SafeTrace Tx function has been designed with patient safety as the highest priority.

Safe Trace Tx offers compatibility testing (electronic, serologic, remote); unique patient identification across facilities for a centralized transfusion service; facility-specific unique patient identifiers; and billing for products, tests and services. SafeTrace Tx is year 2000 compliant.

Security

The Security module controls access to SafeTrace Tx system. SafeTrace Tx's security functions ensure that data entry and data access is available only to authorized personnel. SafeTrace Tx enforces specific access restrictions associated with each user.

Access to SafeTrace Tx is controlled by User login, dependent upon a unique User ID and a secure password. Access to the Security module is available only to authorized personnel. The access granted to a user is controlled by the system administrator.

The Security module is the repository for all user security profiles across all facilities. Maximum login attempts and account statuses also are set up by individual profile. The Security module profiles allow the ability to set up group accounts and assign User IDs at the group level. For each Group ID, access levels may be set up by module and form level.

The Security module also provides the system manager and other authorized users access to the login history of each User ID. Information provided includes login date and time, logout date and time, and the modules accessed.

Audit Capabilities

SafeTrace Tx includes audit tracking and on-line audit review that crosses SafeTrace Tx modules. Auditing is accomplished through functionality built in to the SafeTrace Tx application.

Database, Hardware and Operating Systems

SafeTrace Tx has been designed to operate in a client environment that runs Microsoft Windows 95 or higher or Windows NT Version 3.51 or higher, and Oracle SQLNET 2 or higher; and has a minimum hardware configuration of Intel Pentium 120 MHz. Processor (or equivalent), 1 GB hard drive, SVGA 800 x 600 video card, 32 MB RAM, 10 megabit Ethernet adapter, and a 14" color monitor.

SafeTrace Tx has been designed to operate with an application server that runs Microsoft Windows NT Server Version 3.51 or higher, and Oracle SQLNET 2 or higher; and has a minimum hardware configuration of Intel Pentium 200 MHz. Processor (or equivalent), 2 x 4 GB hard drive, 64 MB RAM, and 10 megabit Ethernet adapter.

SafeTrace Tx has been designed to operate with a database server that runs Oracle RDBMS Version 7.3 or higher, and Oracle SQLNET 2 or higher; and has a minimum hardware configuration of Intel Pentium 200 MHz. Processor (or equivalent), 2 x 4 GB hard drive, 128 MB RAM, and 10 megabit Ethernet adapter.

Significant Performance Characteristics

The significant performance characteristics are Product Quality/Maintainability, System Reliability, and System Speed/Response Times.

Product Quality/Maintainability – Product quality is measured in terms of the number and criticality of anomalies and in the ability to diagnose and correct newly found anomalies. The Wyndgate development process, which adheres to current software design, development and test practices, is a primary factor in minimizing the number of anomalies introduced into the product. This same factor, plus the product design, architecture, standard database and tool sets, are primary factors in the diagnosis and

correction of newly discovered anomalies. Wyndgate's extensive unit, system and beta testing are also large contributors to high product quality and maintainability.

System Reliability – System reliability is achieved by all of the factors listed in Product Quality/Maintainability above, and by the appropriate system hardware/software configurations discussed in Database, Hardware and Operating Systems above. The product architecture and design, along with widely used standard operating platforms (hardware, operating systems and database) ensure high reliability. In addition, the Oracle RDBMS allows for 'hot' (real time) back up of all data, minimizing the potential for data loss. Wyndgate also recommends that each customer use a disk redundancy system in order to ensure data availability.

System Speed and Response Times - The system design, architecture, tool sets, and the minimum database, hardware and software requirements are designed for maximum system response times. Response times can also be greatly effected by customer considerations such as network capabilities.

A5. Statement of Intended Use:

SafeTrace Tx is a comprehensive computer software package that manages the information system needs of a transfusion service. SafeTrace Tx is designed to help transfusion services:

- Manage an inventory of blood for patients.
- Track patient identification information.
- Manage patient visits and specimens.
- Capture orders for patient tests and blood products.
- Track product disposition.
- Determine the suitability of released products.
- Record transfusion results.

SafeTrace Tx maintains a complete test and transfusion history for a patient and comprehensive tracking of donor products from receipt to final disposition.

As shown in Section A3. above, the Intended Use, Features, OS/Database/ Hardware Environments, Other Technological Characteristics and Life-Cycle Activities of SafeTrace Tx and Cerner PathNet are substantially equivalent.

A6. Technological Characteristics

The technological characteristics of a transfusion management information system include the hardware and tool sets used to develop, test, implement, operate and maintain the product, along with the design methodology used during the life cycle of the product. As shown in Section A3. above, the technological characteristics of SafeTrace Tx and Cerner PathNet are substantially equivalent.

B1. Non-clinical (System) Testing

The objective of the system test is to ensure the software system has met the intended use and meets all of the safety critical requirements. This is ensured through mapping the test procedures and test cases to the functional requirements and hazard analysis. The SafeTrace Tx systems testing was performed using test cases that were drafted according to defined test objectives to fulfill test requirements. Each test case is traceable to one or more functional requirements, and each functional requirement is traceable to one or more test cases.

The approach to system testing was to use an automated test tool to test the functional requirements. In addition, for those functional requirements that implement a safety critical requirement, additional manual test procedures and cases were created and executed. The summary of results of these test cases are included in section B3.

Prior to the completion of System Testing, all No Pass (fail) occurrences were resolved (either corrected or scheduled for future correction). All safety critical issues were corrected. Re-execution of each corrected No Pass yielded Pass situations for all occurrences.

In addition to System Test, other verification and validation efforts (unit testing, design reviews, etc.) inherent in Wyndgates software development lifecycle have been performed on SafeTrace Tx to help ensure the safety, quality, identity, potency and purity of blood and blood products and patient safety.

B2. Clinical (Beta) Testing

The purpose of the Beta test was to perform user validation and verification testing of SafeTrace Tx in a user environment prior to the final release of the software. The Institute For Transfusion Medicine (ITxM) in Pittsburgh, Pennsylvania, was the location used to test SafeTrace Tx. The Beta testing

process promotes the identification of errors, inconsistencies and deviations in SafeTrace Tx prior to final software release. As unexpected issues arose, they were addressed by Wyndgate Technologies through the use of Issue Tracking Spreadsheets. Issue Tracking Spreadsheets exist for all SafeTrace Tx modules: Inventory, Patient/Order, Table Administration, and Security.

The beta testing approach was similar to the system level approach in that both automated and manual tests were performed. Manual testing focused on testing the safety critical functionality. The automated testing included testing non-safety related functionality. The results of the beta testing are included in B3.

Prior to completion of Beta Testing, all No Pass (fail) occurrences were corrected or scheduled for future correction. All issues related to the safety critical functionality were corrected. Re-execution of each corrected No Pass yielded Pass situations for all occurrences.

B3. Conclusions of Non-clinical and Clinical Testing

The System and Beta testing described above were two important steps in the overall verification and validation of SafeTrace Tx, Version 1.0.

The following table summarizes manual test results at the System and Beta levels:

Summary of Manual Test Results for System and Beta Testing

	System Test	Beta Test	Total
Total Test Cases	313	138	451
Initial Test Case Failures	9	19	28
Test Case Failures on Re-test	0	0	0

The following table summarizes the results of the automated testing at the system level:

Automated System Testing Results

SafeTrace Tx Module	Number of Test Cases	Number of Test Cases that Did Not Pass at First Run	Number of Times Retests Run to Pass
Patient/Order	16	1	1
Inventory	11	1	1
Table Administration	26	1	1
Security	12	0	0

The following table summarizes the results of the automated testing at the Beta level:

Automated Beta Testing Results

SafeTrace Tx Module	Number of Test Cases	Number of Test Cases that did not Pass at first run	Number of Times Retests Run to Pass
Patient-Order	15	0	0
Inventory	11	0	0
Table Administration	25	0	0
Security	12	0	0

The testing at system and beta levels revealed a relatively low number of initial failures. Each failure was analyzed in terms of impact on safety, effectiveness and its intended use. All failures concerning safety have been corrected. The beta site has reviewed and approved the Beta testing plans and results (see attached letter from ITxM).

In consideration of the above, Wyndgate believes SafeTrace Tx, Version 1.0 has met the expectations for high product quality, is fit for its intended use, and is substantially equivalent to its predicate device.