

Tab 6, 510(k) Summary

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Date summary was prepared: 8/5/04

Name of Device

Proprietary name: Misys Laboratory™ Blood Bank and Blood Donor, version 6.0.1

Common name: Blood Establishment Computer Software

Abbreviated 510(k)

Identification of Legally Marketed Predicate Devices

The Misys Blood Bank and Blood Donor product is substantially equivalent to the following systems:

Predicate Device 1:

Manufacturer:

**Misys Healthcare Systems, formerly Sunquest
Information Systems, Inc.**

Common Name:

Blood Bank System

Trade Name:

FlexiLab[®] Blood Bank and Blood Donor, Version 5.2

510(k) Number:

BK990002 (August 16, 1999)
BK990034 (November 17, 1999)

Predicate Device 2:

Manufacturer:

Wyndgate Technologies

Common Name:

Transfusion Service Management Information System

Trade Name:

SafeTrace Tx[™], Version 1.0

510(k) Number:

BK980023 (January 29, 1999)

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Device Description

The blood bank and blood donor software operates on general-purpose hardware supplied by commercial manufacturers and is composed of functions written in standard Microsoft Visual Basic, Microsoft Visual C++, and Caché languages. Data is stored in Caché globals. Users define database tables during a process of planning and data entry known as "system maintenance," which is part of system implementation and ongoing maintenance.

The Misys Blood Bank and Blood Donor software is divided into subsections or "functions". Each function requires a user-defined security level, which allows the user to control data security and integrity. The system is marketed as a subsystem to the Misys Laboratory software product as well as a stand-alone product. This product is only intended to be used by professionals who have received extensive training in the use of the software.

The Blood Donor application includes the following capabilities:

- Donor registration
- Donor evaluation record (results from donor testing and questionnaire responses)
- Donor prescreen record
- Combined functions that are available to streamline individual site operations
- Miscellaneous user-defined prompts and response validations
- Suppressed display of confidential deferrals
- Automatic status change for the units from confidential deferrals
- Duplicate donor checking and merge capabilities
- Updating of permanent donor records from unit testing results (such as blood type)
- Specific identification and requirements for directed and autologous donors
- Autologous and directed unit assignment
- User-defined donor cards and letters
- Phlebotomy data
- Inquiry

The Blood Bank application includes the following capabilities:

- Inventory control
- Patient history
- Product history
- Autologous/directed unit tracking
- Patient testing
- Product testing
- Patient and product testing transmitted from blood bank analyzers
- Component preparation
- Electronic crossmatching
- Product dispensing data evaluation
- User-defined unit tags
- Inquiry

Misys clients are configured with hardware components based on the specific needs of their laboratory, such as number of interactive users, the software modules they purchase, and their overall workload. Depending on their existing infrastructure, sites can choose from the hardware configurations.

Intended Use

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 release 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 qualifying patients for electronic crossmatch
 - Perform quality assurance checks and maintain quality assurance records
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**510(k) Summary
Comparison of Technological Characteristics**

	Misys Laboratory Blood Bank and Blood Donor, Version 6.0.1 (Misys)	FlexiLab® Blood Bank and Blood Donor, Version 5.2 (Misys/Sunquest)	SafeTrace Tx™, Version 1.0 (Wyndgate)
Operating Environment	<ul style="list-style-type: none"> InterSystems Cache' post relational database version 4.1.12 and 4.1.16 UNIX IBM AIX (Version 5.1) operating systems (database and application server) Microsoft Windows 2000 or XP Professional (client processing environment) 	<ul style="list-style-type: none"> InterSystems MUMPS database, version 6.4-f14 UNIX DEC (Version 4.0) IBM AIX (Version 4.2), and Hewlett Packard Open VMS (Version 6.2) operating systems. 	<ul style="list-style-type: none"> Oracle Relational Database Management System, version 7.3. UNIX and Windows NT Operating Systems. Microsoft Windows NT
Programming Language	Visual Basic, Visual C++, Cache'	MUMPS	Delphi, SQL
Input	Barcode scanner, keyboard, and interfaces with blood grouping instruments	Barcode scanner and keyboard	Barcode scanner, keyboard, interfaces with blood grouping instruments
Table Administration	Allows user with security authorization to add, update, or outdate data. Provides functionality to build user-defined tables. Prints hard-copy listing of each table and its contents.	Allows user with security authorization to add, update, or outdate data. Provides functionality to build user-defined tables. Prints hard-copy listing of each table and its contents.	Allows user with security authorization to add, update, or outdate data. Provides functionality to build user-defined tables. Provides hard-copy listing of each table and its contents. Contains administrative functions for the maintenance of tests, products, services, and providers.

Abbreviated 510(k)

	Misys Laboratory Blood Bank and Blood Donor, Version 6.0.1 (Misys)	FlexiLab® Blood Bank and Blood Donor, Version 5.2 (Misys/Sunquest)	SafeTrace Tx™, Version 1.0 (Wyndgate)
Data Backup/Restore	Data archival and retrieval via system level backups.	Data archival and retrieval via system level backups.	Data backup
Access security	Manages user ID and password combinations. Manages access to system across and within facilities. Maintains login histories.	Manages user ID and password combinations. Manages access to system across and within facilities. Maintains login histories.	Manages user ID and password combinations. Manages access to system. Maintains login histories. Repository for all user security profiles across all facilities.
Audit Trail	Comprehensive history of all changes to blood product data. Data accessible for review via on-line inquiry screen and blood product history report.	Comprehensive history of all changes to blood product data. Data accessible for review via on-line inquiry screen.	Audit data changes. Review audit records

Description and Conclusions of Testing

The Misys 6.0.1 software was developed and validated using established procedures for software development. As such, it is anticipated that this system is as safe and effective as, and will perform as well as or better than the identified predicate devices when utilized within its intended use, as verified by the clinical and non-clinical testing that was performed.

Non-Clinical Testing

The Misys 6.0.1 software was developed and validated using established procedures for software development. As such, it is anticipated that this system is as safe and effective, and will perform as well as the identified predicate devices when utilized within its intended use, as demonstrated by the clinical and non-clinical testing performed.

Unit, functional (including integration) and regression testing was performed internally by Misys Development and Quality Control Personnel. Misys Healthcare's unit testing focuses on structural tests constructed by analysis of portions of the code related to safety critical functions and defining tests to verify each identified line of code executes properly. Misys Healthcare's functional testing focuses on ensuring the application under test meets the requirements set forth in the requirements document(s) and ensures all functions can be executed without any patient risk or hazard. Misys Healthcare's regression testing focuses on retesting software to ensure that modifications have no adverse affect on non-related functionality.

The assessment of this testing verified that the Misys Blood Bank and Blood Donor software, Version 6.0.1 design input requirements were met.

Clinical Testing

Misys 6.0.1 software Beta testing was performed in a user environment against a user database. The Misys 6.0.1 general testing guideline was the basis for executing this client testing. The assessment of this testing verified that the Misys Blood Bank and Blood Donor software, Version 6.0.1 met the required specifications and functioned as intended.

In addition, Misys ensures that all safety critical items are thoroughly tested and can demonstrate that all methods of control for intended use and general implementation hazards have been tested.
