



510(k) Summary

DEVICE NAME: Sunquest Blood Bank and Blood Donor

COMMON NAME: Blood Establishment Computer Software

PROPRIETARY NAME: Sunquest Blood Bank and Blood Donor

SOFTWARE VERSION: 8.0

DATE SUMMARY PREPARED: 13 January 2016

Establishment Information

ESTABLISHMENT Registration:
2029302

OWNER/OPERATOR NUMBER:
9010587

MANUFACTURER INFORMATION:
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Predicate Device:

Manufacturer:	Sunquest Information Systems
Common Name:	Blood Establishment Computer Software
Trademark Name:	Sunquest Blood Bank and Blood Donor
Software Version:	6.4
510(K) Number:	BK080042

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 Intersystems 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 Sunquest 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 Sunquest 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
- Printing Unit number labels
- Reading and printing of ISBT 128 labels

- Emergency issue of blood products

Sunquest client systems 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.

The following modifications have been made since the last submission:

- **UK Rules update.** This installable feature prevents users from allocating ABO incompatible units, but allows allocation of non-identical ABO but compatible units with override.
- **Enhancements to Blood Order Processing.** This feature ensures that QA Failures are not generated unnecessarily, reducing interruptions to the user workflow.. It also rearranges UI elements to make better use of screen real estate.
- **ISBT 128 product code capture.** This feature captures and stores the eight-character ISBT 128 product code value for units at issue.
- **Emergency Release.** This feature allows users to allocate and issue blood on an “emergency release” basis for patients with known and unknown blood types, with limited QA failures. It also supports Mass Transfusion Protocol (MTP) by enabling simultaneous issue of units for multiple orders.
- **Other miscellaneous changes.** This feature enables users to document additional Visual Inspection and Temperature Check activities in system. In addition, the user is able to print blank unit tags.

Comparison of Intended Use

There has been no change to the intended use of the Blood Bank and Blood Donor product since the previous release. The intended use is:

The Blood Bank and Blood Donor System is intended for use by trained healthcare professionals responsible for donor and transfusion services.

Comparison of Indications for Use

Sunquest Blood Bank and Blood Donor, Version 8.0	Sunquest Blood Bank and Blood Donor, Version 6.4
<p>Blood Bank Blood Bank is intended for use by trained health care professionals responsible for transfusion services. It is intended for use to:</p> <ul style="list-style-type: none"> • Store records of manufactured and blood product component preparation. • Print ISBT 128 blood product labels for finished and further processed blood products and products intended for transfer. • Record the release of manufactured and blood products for infusion. • Maintain manufactured and blood product inventory for lookback. • 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. • Display data required to assist health care professionals when qualifying patients for electronic crossmatch. <p>Blood Donor Blood Donor is intended for use by trained health care professionals responsible for donor services. It is intended for use to:</p> <ul style="list-style-type: none"> • Display data that assists health care professionals in making decisions regarding the suitability of donors. • Generate deferrals to the donor record and maintain donor records. • Maintain phlebotomy records. 	<p>The Blood Bank and Blood Donor system is intended for use by blood establishment donor and transfusion service personnel in the following ways:</p> <ul style="list-style-type: none"> • 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 • Print ISBT 128 blood product labels for finished and further processed blood products and products intended for transfer. • 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

Comparison of Major Functions

Function	Sunquest Laboratory Blood Bank and Blood Donor, Version 8.0	Sunquest Laboratory Blood Bank and Blood Donor, Version 6.4
Track Donor Deferrals/Eligibility	X	X
Store Donor Antibody/Antigen Testing Results	X	X
Record Donor ABO/Rh	X	X
Product/Unit Inventory	X	X
Autologous/Directed Unit Tracking	X	X
Donor Recruitment	X	X
Direct Entry of Test Results	X	X
Track all steps in production of product	X	X
Antigen Typing	X	X
Management Reports	X	X
Crossmatch Results	X	X
Supports scanning of ISBT 128 unit labels for data entry	X	X
Source/Recovered Plasma Management	X	X
Bar Code reading wherever unit number is entered	X	X
Interface with blood grouping machines	X	X
Electronic cross-match qualification	X	X
Supports printing of ISBT 128 labels	X	X
Emergency Issue of blood products	X (New in version 8.0)	N/A

Comparison of Technical Characteristics

Characteristics	Sunquest Laboratory Blood Bank and Blood Donor, Version 8.0	Sunquest Laboratory Blood Bank and Blood Donor, Version 6.4
Operating Environment	<p>InterSystems Caché post relational database version 2012 (1.2) and 2014</p> <p>UNIX IBM AIX (Versions 6.1 and 7.1) operating systems (database and application server)</p> <p>HP – UX (Version 11i v3) operating system (database and application server)</p> <p>Microsoft Windows Server 2008 R2 SP1 Microsoft Windows Server 2012 R2</p> <p>Microsoft Windows 7 Service Pack 1 (client processing environment) Microsoft Windows 8.1, 64-bit (client processing environment)</p> <p>The following systems have reached “End of Life” and are no longer supported:</p> <p>ALPHA UNIX TRU64 ALPHA OPEN VMS</p>	<p>InterSystems Caché post relational database version 5.0.21</p> <p>UNIX IBM AIX (Version 5L 5.2 and 5.3) operating systems (database and application server)</p> <p>HP – UX (Version 11i v2) operating systems (database and application server)</p> <p>Microsoft Windows Server 2003 SP2</p> <p>Microsoft Windows 2000 Service Pack 4(client processing environment) Microsoft Windows XP Service Pack 2 or Service Pack 3 Professional (client processing environment) ALPHA UNIX TRU64 (Versions 5.1a and 5.1b) operating systems (database and application server)</p> <p>ALPHA OPEN VMS (Version 7.3-1 and 7.3-2) operating systems (database and application server)</p>
Programming Language	Visual Basic, Visual C++, Caché	Visual Basic, Visual C++, Caché
Input	Barcode scanner, keyboard, and interfaces with blood grouping instruments	Barcode scanner, keyboard, and 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.
Data Backup/Restore	Data archival and retrieval via system level backups.	Data archival and retrieval via system level backups.
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.
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 and blood product history report.

Description and Conclusions of Testing

The design control activities have been performed to ensure that safety and performance are substantially equivalent to the predicate device. The Sunquest Blood Bank and Blood Donor, Version 8.0 software was developed and validated using established procedures for software development. Based upon the verification and validation activities performed, Sunquest Blood Bank and Blood Donor software has been demonstrated to be safe and effective when utilized within its intended use.

Non-Clinical Testing

The Sunquest Blood Bank and Blood Donor 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 device when utilized within its intended use, as demonstrated by the clinical and non-clinical testing performed.

Unit, functional, and system testing were performed internally by Sunquest Development and Quality Control Personnel. 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. Functional testing ensures the application under test meets the requirements set forth in the requirements document(s) and all functions can be executed without any patient risk or hazard. System testing covers regression, compatibility, performance and ignition testing. Regression testing focuses on retesting software to ensure that modifications have no adverse effect on non-related functionality. Compatibility testing ensures the application operates in specified environments. Performance testing ensures the responsiveness and reliability of the system under given operating workloads. Ignition testing ensures the successful installation and/or upgrade of the software. Sunquest maintains traceability analysis for each testing type to ensure adequate testing coverage. The assessment of this testing verified that the Sunquest Blood Bank and Blood Donor software, Version 8.0 design input requirements were met.

Clinical Testing

Testing was performed in a user environment against user's database during user testing. The assessment of this testing verified that the Sunquest Blood Bank and Blood Donor software, Version 8.0 met the required specifications and functioned as intended.

Conclusion

It is the conclusion of Sunquest Information Systems that Sunquest Blood Bank and Blood Donor, Version 8.0 is substantially equivalent to and as safe and effective as the predicate device.

Revision History

Revision Number	Revision Date	Description of Revision	Revision Author
1.0	13 January 2016	Baseline Document	Amy Beyer
2.0	22 March 2016	Updated Indications for Use	Amy Beyer