

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Submitted By:

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Device Name

Proprietary Name: Systematic Blood Bank (SBB) Software

Common Name: Blood Bank Software

Classification Name: Software, Blood Bank, Stand Alone Products (81MMH)

Intended Use

The Psyche Systems Corp.'s SBB software is used for the management of patient and unit records in a blood bank system. It does not include a blood donor module.

Device Description

The Psyche Systems Corp.'s SBB software is integrated as a module in the Laboratory Information System (LIS). It is written in Fortran and runs on Digital Corp. VAX/Alpha architectures using the OpenVMS operating system. It is designed for patient and unit records management in a blood bank system. It does not include a donor module.

SBB standardizes record keeping for:

- test result entry
- patient information
- product information
- transaction histories

SBB provides extensive error checking during:

- test result entry
- patient management
- product management

SBB provides routine and on-demand reports covering:

- patient histories
- current results
- product inventory status

Major features of SBB include:

Permanent on-line storage of patient and product records. Offline record storage on tapes or disks for long-term reporting.

Product inventory for American Red Cross (ARC), ISBT128, and non-ARC units, and directed and/or autologous donations.

Pooled and split product capability. Workscreens assist in selecting units for pooling and in calculating each split volume.

Product reservation system. Available units are ranked by compatibility, age of product, etc.

Substantial Equivalence Claim

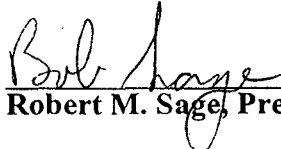
Psyche Systems Corp.'s SBB software is similar in indications, design and features to various other Blood Bank management software in the market that FDA has found to be substantially equivalent to the pre-amendment devices. The following are some such devices:

Manufacturer	Product	510(k) Number
Shared Medical Systems	SMS Blood Bank Transfusion System Version 4.0/4.1/4.2/4.3	BK960036
Sunquest Information Systems, Inc.	Flexilab Blood Bank Transfusion System	BK990034
Cerner Corporation	PathNet Blood Bank Transfusion Version 306	BK950053
Wyndgate Technologies	SafeTrace TX, Version 1.0	BK980023

The following table compares the use and features of Psyche Systems Corp.'s SBB software with those of an equivalent Blood Bank Transfusion System – SMS Blood Bank Transfusion System.

	Psyche Systems Corp.	SMS
Product labeling	Blood Bank Transfusion System	Blood Bank Transfusion System
Intended Use	Management of patient and unit records in a blood bank. This includes the recording of blood bank tests (antibody screens, crossmatches, and blood group and type), the storage of information associated with blood components (use in pooled units, crossmatches, status and disposition), supplier identification, expiration dates, patient information, patient histories, and reports.	Management of patient and unit records in a blood bank. This includes the recording of blood bank tests (antibody screens, crossmatches, and blood group and type), the storage of information associated with blood components (use in pooled units, crossmatches, status and disposition), supplier identification, expiration dates, patient information, patient histories, and reports.
Operating Environment	OpenVMS on DEC VAX or Alpha architectures	DEC Alpha/Vax architectures
Programming Language	Fortran	Mumps
Major Functions	<ul style="list-style-type: none"> • Patient Information • Product Information • Test Results Entry • Transaction Histories • Reports 	<ul style="list-style-type: none"> • Patient Information • Product Information • Test Results Entry • Transaction Histories • Reports
Input	Bar-code scanner and keyboard	Bar-code scanner and keyboard
Error Checking	In patient management, product management and test result entry functions	In patient management, product management and test result entry functions
Data Security	Data archival and retrieval routines included	Data archival and retrieval routines included
Access Security	Administrator and user level access control included	Access control
Audit Trail	Permanent transaction log	Audit trail for supervisory review

The determination of substantial equivalence is not based on an assessment of any performance data, clinical or non-clinical.



 Robert M. Sage, President

4-Jun-2001

 Date