HMS™

510 (K) Summary

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SUBMITTER'S NAME:

Healthcare Management Systems, Inc.
3102 West End Ave. Suite 400
Nashville, TN 37203
615-383-7300

CONTACT PERSON:

Patricia Willoughby, Ph.D.
Senior Product Manager, Product Development Group
Healthcare Management Systems, Inc.
Phone: 615-383-7300 ext. 2347
Fax: 615-386-6662

DEVICE NAME:

Proprietary Name: Blood Administration Module

Common Name: Software, Blood Transfusion Services

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

PREDICATE DEVICE

Blood Administration Module is substantially equivalent in its intended use and features to the Psyche Systems Corporation's Systematic Blood Bank (SBB) Software Version 3.0 marketed as BK010017.

DEVICE DESCRIPTION

The HMS Blood Administration module is designed to assist an acute care hospital in documenting the disposition of blood components issued to patients, and in capturing all appropriate charges for the testing and distribution of blood components to the patients. It is a software device that requires knowledgeable user intervention by competent medical personnel to document the activities or steps and events occurring in a transfusion service. This module was designed to be used as an integrated part of HMS' hospital information system.

The Blood Administration module was designed to run on an IBM i-Series hardware platform. The RPG programming language is the primary programming language of the software. The RPG language is used in combination with SQL, CL, and Java to provide extremely fast access to the database and for efficient processing of the tasks performed in the transfusion service.

The individual user is connected to the system via a network connection from a PC. The PC should run on Windows network software, version 2000 Professional Operating System.

Operating systems used in alpha and beta testing consisted of:

Windows 2000 Professional – Service Pack 3
Windows 2000 Professional – Service Pack 4
Windows XP Professional – Service Pack 1
Windows XP Professional – Service Pack 2
Windows 2000 Server – Service Pack 3
Windows 2000 Server – Service Pack 4

Personal computers used in alpha and beta testing consisted of:

DESKTOPS:
Pentium 4 processor; 256 mb; 20G; 10/100 ethernet
Pentium 4 processor; 512 mb; 20G; 10/100 ethernet
Pentium 3 processor; 128 mb; 10G; 10/100 ethernet
Pentium 3 processor; 256 mb; 10G; 10/100 ethernet
Celeron processor; 128 mb; 10G; 10/100 ethernet
Celeron processor; 256 mb; 10G; 10/100 ethernet

LAPTOPS:
Centrino processor; 256 mb; 10G; 10/100 ethernet
Centrino processor; 512 mb; 20G; 10/100 ethernet

SERVERS:
Zenon processor; 3 gb; 80G; 10/100/1000 ethernet
Celeron processor; 1 gb; 20G;10/100 ethernet

SeaGull™ is the graphical user interface program used to supply the displays, fields and function keys utilized in the Blood Administration module.

INTENDED USE

The HMS Blood Administration module is an integrated, computerized system intended to be used by trained laboratory personnel as an aid in the entry and computer storage of information related to patient testing in a transfusion service, and for the capture of charges related to the testing and distribution of blood components to patients for transfusion.

Major features of the module and its 'Indications for Use' are:

1. Allow controlled access to the Blood Administration module.
2. Receive orders for blood testing and blood products electronically.
3. Enter of patient testing results for blood type, antibody screens and other Blood Bank procedures manually.
4. Record the entry of crossmatch results of a blood or blood component to a patient.
5. Allow the user to issue blood products under normal and emergency conditions.
6. Track the disposition of blood components from the time a blood component has been crossmatched to a patient, through the release of the blood component for transfusion purposes, and records the final disposition of the blood or blood component.
7. Provide result reports to the physician and other appropriate clinicians.
8. Provide management reports provide information on the disposition of all blood components, the detail a patient's transfusion history, or the history of a specific unit number.

The system is not designed, nor is it intended, to be used for recording of donor information, for recording results of infectious disease testing with any donor or donor unit of blood components, or for the processing and labeling of blood components intended for distribution to hospitals and other transfusion services.

COMPARISON OF CHARACTERISTICS TO PREDICATE DEVICE

The use and features and the technological characteristics are similar in that both of the systems are intended for use by transfusion services within a hospital setting.

PREDICATE DEVICE:

Psyche Systems Systematic Blood Bank (SBB) Version 3.0 (BK010017).

A. Uses and Features Characteristics Comparison

The following table compares the uses and features of HMS' Blood Administration module with those of an equivalent Blood Bank Transfusion System: Psyche Systems Corp.'s Systematic Blood Bank (SBB).

AREAS OF COMPARISON	SIMILARITIES	DIFFERENCES
1. Product Labeling	Blood Administration Module and Psyche SBB Transfusion Service Module are designed to be used by a Laboratory Transfusion Service.	
2. Intended Use	Blood Administration Module and Psyche SBB software are used by laboratory professionals to record the patient testing results of common Blood Bank procedures, i.e. blood type, antibody screens and crossmatches. The Blood Administration Module and Psyche SBB provide for the electronic storage of this information for future use. Additionally, Blood Administration Module and Psyche SBB software do not include a donor module, and are not intended to be used for the recording of donor information or the association of infectious disease testing with any donor or donor unit.	Blood Administration Module is intended to be used only as an integrated module to the Laboratory Results Reporting System. Psyche SBB software can be used as an optional module to LabWeb, and as a standalone hosted blood bank solution.
3. Hardware Platform		IBM i-Series Psyche SBB - Digital DEC VAX or Alpha architectures
4. Software Language		Blood Administration module is written in RPG with SQL, CL, Java and Seagull™ GUI interface Psyche SBB is written in Fortran using OpenVMS operating system.

5. Software functionality	Blood Administration Module and Psyche SBB are designed to record the results of patient testing with historical lookback of results. Display patient historical files. Provides useful management reports of the disposition and usage of blood components, and the patient/unit history information.	
6. Input	Blood Administration Module and Psyche SBB utilize keyboard and bar code entry of data.	
7. Output	Blood Administration Module and Psyche SBB use CRT's and printers for output.	Blood Administration Module may be displayed using a network thin client presentation.
8. Data Security	Blood Administration Module has daily data backup and a recovery process, if needed. Psyche SBB has data archival and retrieval routines included.	
9. Access Security	HMS provides Administrator and user level access controls. Psyche SBB provides Administrator and user level access controls.	
10. Audit trail	HMS has a permanent transaction audit log. Psyche SBB utilizes a permanent transaction log.	

B. Technical Characteristics Comparison

The following table compares the technical characteristics of HMS' Blood Administration module with those of an equivalent Blood Bank Transfusion System: Psyche Systems Corp.'s Systematic Blood Bank (SBB).

AREAS OF COMPARISON	Blood Administration Module	Psyche Systematic Blood Bank Software
Unit inventory	No	Yes
Autologous and directed unit tracking	Yes	Yes
Crossmatch results	Yes	Yes
Print donor unit labels-bar coded	No. Blood Administration module is not a donor processing module.	Yes
Full support of ISBT 128 unit labeling	No. Blood Administration module is not a donor processing module.	Yes
Bar-code reading of donor and unit information	No	Yes
Ad hoc report writer	Yes	Yes
Accounts Receivable	Yes	No
Management reports	Yes	Yes
Direct entry of patient test results	Yes	Yes
Electronic crossmatch decision making	No	Yes
Track all steps in production of product	No. Blood Administration module is not a component processing module.	Yes
Antigen typing	Yes	Yes
Centralized transfusion services	No. Blood Administration module is not a donor or component processing module	Yes
Hand-held devices for positive patient ID	No	No

System provides standard ASTM/HL7 interface	Yes	Yes
Connectivity	VPN, local client, remote client	Telnet, local client, remote client, Web client
Tools to help client validate their system	Documentation and training	Documentation and training
Complete blood bank ASP solution	HMS provides an ASP solution for their HIS	Yes
Integrated with the hospital information system	Blood Administration module is an integral part of the HMS HIS. It is not sold separately.	Besides being offered as an optional module, SBB is also available as a standalone hosted blood bank solution.
Inventory management system	No inventory management capabilities exist at this time.	Automated inventory management solution available as part of SBB

SOFTWARE VERIFICATION AND VALIDATION DATA

The Blood Administration module was developed using an established protocol for software development. The software verification and validation processes used to program and test the HMS Blood Administration module are described in the Healthcare Management Systems Controls Document found in Section I (pages I.1 – I.8). These software verification and validation processes provided confidence that the HMS Blood Administration module meets its intended goals as described in the Indications for Use (Section D.1), and will provide improved patient care through increased safeguards on patient safety and workflow efficiencies while assisting our clients in meeting their regulatory compliance requirements.

SAFETY AND EFFECTIVENESS DATA

This system has been tested for the safety and effectiveness in house during the programming phase, by the Quality Assurance department, and during the alpha testing phase at one client site. This was followed by a beta testing period at 5 client hospitals.

The following areas of the Blood Administration module were evaluated at the client beta test sites:

1. Entry and receipt of patient orders.
2. Entry of patient results for Blood type, Antibody screen and Crossmatch testing. (Minimum of 500 patient samples.) See table.
3. Patient report generation.

The following table summarizes client test results for the clinical beta testing of the Blood Administration module.

HOSPITAL	DAYS	# of Pts.	Blood Type	Antibody Screen	Crossmatches
Carthage General Hospital	30	46	24	20	95
Regional Hospital of Jackson	21	148	4	126	139
Volunteer Regional Hospital	21	85	17	54	68
Dyersburg Memorial Hospital	21	95	23	57	134
Province-Vaughan	21	176	22	133	251
GRAND TOTAL		550	90	390	687

See Section I. Validation, Verification and Testing for detailed information for each client site that participated in the testing of the HMS Blood Administration module.

EVALUATION OF THE SAFETY AND EFFECTIVENESS DATA

The Blood Administration module was evaluated at 5 client hospitals. Calls to Product Development or Clinical Customer Support reporting possible software issues, or requesting product enhancements were documented. These calls were acted upon following standard HMS procedures. See the Programming Information Form (PIF) Cycle document in Section I (pages I.9 to I.13) for the standard HMS process. During this evaluation period the number of software problems reported decreased at each successive site with no reported software anomalies at the last 2 sites.

The outcome from in-house and user site testing demonstrated that no significant patient testing anomalies affecting patient safety were found, and that the HMS Blood Administration module works as intended when the module is used for its stated purposes.

Additional test data is in Section I. Verification, Validation and Testing and is available upon request.

CONCLUSION

Verification testing demonstrates that the design outputs meet the design inputs fulfilling all design specifications. Alpha and beta testing demonstrate that the intended use is met, the functional requirements are fulfilled and the device is safe and effective.

The conclusions drawn from the nonclinical and clinical tests demonstrate the HMS Blood Administration Module is substantially equivalent to the predicate device when utilized within its intended use.