Special 510(k) Summary

Date Prepared: May 11, 2010
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Device Class: Unclassified

Device Name:

Proprietary Name: SoftBank II Version 25.1
Classification: Software, Blood Bank, Stand Alone; (Product Code MMH)

Predicate Device: SoftBank II Version 25, BK090017

Device Description:

SoftBank II Version 25.1 was designed to enable the utilization of the current application with additional functionality including label verification of manufactured components, and the ability to add special messages onto a patient's record based on the ordered blood product. The functionality of the predicate device, SoftBank II Version 25 (BK090017), is the foundation on which the added functionality was designed. All of the previous functionality of the SoftBank II application is intact.

Intended Use:

The SoftBank II application is an unclassified FDA regulated medical device that is to be used in a clinical laboratory setting by knowledgeable, trained medical and healthcare personnel. The SoftBank II application, using SoftScape user interface, is a decision support software device that requires knowledgeable user intervention to document steps and events in a transfusion service. The application provides single and multiple site facilities the ability to manage their transfusion service by integrating patient and unit information.

SoftBank II supports the following functionality:

- Compatibility of blood products with recipient to include decision support
- Electronic compatibility determination of blood products while maintaining decision support capability
- Inventory management of blood, components, tissue, and derivative products
- Tracking of blood, components, tissue, and derivative products from receipt to final disposition
- Documenting receipt of reagents used in testing and recording the test results for daily reagent quality control
- Interfacing with automated blood bank instruments allowing the transfer of results and interpretations from the instrument to SoftBank II

- On-line reporting to assist in utilization management

SoftBank II does not support the following functionality:

The application does not support the procurement, testing, packaging, and processing activities for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P).

SCC Soft Computer does not support use of this product beyond the intended use stated in this section. Use of this product outside of the intended use is a violation of the Code of Federal Regulations on Labeling (21 CFR 801).

FDA has not cleared or reviewed this software for use with tissue products.

Design Control Activities Summary

SCC Soft Computer's activities to assure adherence to design control include determining new risks introduced by the new functionality and analyzing that hazard using Failure Modes Effect Analysis (FMEA). Hazards are mitigated by identifying new requirements to reduce the hazard or provide appropriate warnings to the user or adding warning statements to the documentation.

Based on the identified hazards and requirements, test cases are written and executed to verify that the proper warnings or mitigations to the hazard have been implemented as stated in the requirements. The hazards, requirements and associated test cases are linked using the DOORS tool to create a requirements traceability matrix. The traceability matrix for the new functionality along with the test case names is provided in 11-D and the requirements in 11-E. The verification and validation output documents are provided in section 11-H, along with the testing summaries and acceptance criteria. Regression testing for the entire product was also performed to demonstrate that the software still functioned correctly and as designed.

Comparison of Functional Characteristics of Predicate Device to SoftBank Version 25.1:

Areas of Comparison	SoftBank Version 25 BK090017	SoftBank Version 25.1
Product Inventory Management		
Capable of receipt of inventory from an outside source, Codabar & ISBT labeled products; Prints ISBT product labels for products modified in the blood bank.	√	√
Provides multi-site inventory control.	√	√
Provides the option of electronic transfer of product delivery files from the supplier when properly formatted.	√	√
Provides record keeping on component modification including tracking of supplies used in the modification process.	√	√

Areas of Comparison	SoftBank Version 25 BK090017	SoftBank Version 25.1
Generates exceptions when a product is returned or transferred with an unacceptable condition code for quality management and improvement.	√	√
Provides label verification for production of new components and component modification.		√
Product Testing		
Records the confirmatory testing on the units.	√	√
Records antigen testing on the units.	√	√
Allows different retype tests to be defined based on the blood type of the unit at delivery.	√	√
Patient Testing		
Records patient-related testing such as ABO/Rh and antibody screens.	√	√
Documents compatibility between patients and products.	√	√
Records release of products for transfusion to recipients.	√	√
Supports documentation of compatibility by providing the ability to record crossmatch results.	√	√
Allows for the electronic determination of compatibility while maintaining decision support capability.	√	√
Searches the database for all similar patients and links or unlinks patients based on current information.	√	√
Alerts the user to previously documented requirements of linked patients.	√	√
Provides criteria qualification for neonatal compatibility checking at the order level.	√	√
Provides criteria qualification for mother and neonate to determine crossmatch and antibody screen requirements.	√	√
Provides direct matching for neonates to issue a blood product	√	√

Areas of Comparison	SoftBank Version 25 BK090017	SoftBank Version 25.1
Modifies specimen outdate after an outpatient patient is transfused or the product status is presumed transfused.	√	√
Provides for expanded demographic fields such as name, ward and medical record number.	√	√
Adds special messages, such as leukoreduced and irradiated, to the patient's record and the patient's caution window based on manual entry.	√	√
Adds special messages, such as leukoreduced and irradiated, to the patient's record and the patient's caution window based on product ordered.		√
Alerts and Warnings		
Warnings are provided to alert the user at various control points in the selection process.	√	√
Warnings are provided to alert the user at various control points in the issuance process.	√	√
Warnings are provided to include locking of patient records when vital data can be changed.	√	√
Allows more than one user to access the record only in sub-options that do not allow change of critical patient information.	√	√
Transfusion		
Records final disposition of a product to include documentation of transfusion to recipients.	√	√
Provides the ability to perform a transfusion reaction workup in the presence of an adverse event.	√	√
Supplies/Rx Products		
Documents receipt of reagents used in testing.	√	√
Records the test results for daily reagent quality control.	√	√
Documents receipt of derivative products.	√	√

Areas of Comparison	SoftBank Version 25 BK090017	SoftBank Version 25.1
Records the assignment and issuance of derivative products to patients.	√	√
Provides control over supply and Rx products delivery, with ability to review package inserts, receipt criteria, and 'ok to use' flags.	√	√
Multisite Workflow & Reports		
Provides complete multi-facility workflow over multiple time zones, along with management and reporting including generation of management and inventory reports to assist the user in the supervisory role.	√	√
Interfaces		
Provides the ability to interface with automated blood bank instruments.	√	√
Accesses other databases such as Oracle™.	√	√
Utilizes SoftScape user presentation layer.	√	√
Provides interface to irradiation devices for documentation of irradiated inventory.	√	√
Centralized Compatibility Testing		
Provides segment tracking for use in centralized transfusion services to allow performance of compatibility testing to be performed in a single location.	√	√
Provides for distribution of the blood product from a remote location.	√	√
Inventory of Product Label Formats		
Provides for Codabar and ISBT blood product labels.	√	√
Allows for receipt of ISBT labeled blood products.	√	√
Accommodates all field specifications for ISBT.	√	√
Allows for expanded blood product extension code field to handle divided units per specifications.	√	√

We conclude that SoftBank II Version 25.1 employs the same or very similar types of technological characteristics as the predicate device including computer technology, hardware, computer operating system, database and related software.

Comparison of Technological Characteristics of Predicate Device to SoftBank Version 25.1:

Areas of Comparison	SoftBank Version 25 BK090017	SoftBank Version 25.1
CPU	IBM RS/6000 Model 150	IBM RS/6000 Model 150
Memory (Ram)	1 GB (2GB for clients with Oracle and more than 2000 requisitions per day)	1 GB (2GB for clients with Oracle and more than 2000 requisitions per day)
Disk Space	For a single CPU with mirror, (4) 9.1 GB Hard Disks. The first (2) 9.1 GB disks will contain the Operating system and programs. The third 9.1 GB (18 GB for clients with Oracle and more than 2000 requisitions per day) disk will hold data and the fourth will be the mirror data disk. For a dual CPU, (3) 9.1 GB hard disks on each system. Two of the 9.1 GB hard disks will contain the operating system and programs while the third 9.1 GB (18 GB for clients with Oracle and more than 2000 requisitions per day) disk will hold data.	For a single CPU with mirror, (4) 9.1 GB Hard Disks. The first (2) 9.1 GB disks will contain the Operating system and programs. The third 9.1 GB (18 GB for clients with Oracle and more than 2000 requisitions per day) disk will hold data and the fourth will be the mirror data disk. For a dual CPU, (3) 9.1 GB hard disks on each system. Two of the 9.1 GB hard disks will contain the operating system and programs while the third 9.1 GB (18 GB for clients with Oracle and more than 2000 requisitions per day) disk will hold data.
Operating System	IBM AIX Version 5.1	IBM AIX Version 5.1
Oracle Software	Oracle 9.2	Oracle 9.2
SCC Software	SoftBank II Version 25 SoftBCL Version 1.0	SoftBank II Version 25.1 SoftBCL Version 1.0 or 1.1

Areas of Comparison	SoftBank Version 25 BK090017	SoftBank Version 25.1
PC	Pentium III 850 MHz 512 MB RAM 5.0 GB HD 100 Mb/s network adapter 1024 x 768 256 colors display Windows XP	Pentium III 850 MHz 512 MB RAM 5.0 GB HD 100 Mb/s network adapter 1024 x 768 256 colors display Windows XP
Peripherals	Bar Code Reader –Intermec Scan Plus 1800 Dot Matrix Printer-OKI MICROLINE 320 Turbo Thermal Label Printer (for Blood bag labels)-Zebra S600 Label Printer using ZPL II that prints 300 dpi (for ISBT labels) – Zebra Z4M Hema Trax.LPS ISBT-128 TCP/IP Print Server (when Hema Trax labeling is used) Digi-Trax Enhanced Zebra Z4M (300 dpi) printer (when Hema Trax labeling is used)	Bar Code Reader –Intermec Scan Plus 1800 Dot Matrix Printer-OKI MICROLINE 320 Turbo Thermal Label Printer (for Blood bag labels)-Zebra S600 Label Printer using ZPL II that prints 300 dpi (for ISBT labels) – Zebra Z4M Hema Trax.LPS ISBT-128 TCP/IP Print Server (when Hema Trax labeling is used) Digi-Trax Enhanced Zebra Z4M (300 dpi) printer (when Hema Trax labeling is used)

Alpha Testing
The objective of alpha testing was to ensure the system had met its intended use and implementation of all new requirements was successful. Software requirements, corresponding test cases, and any related hazards were linked and can be viewed in the Traceability Matrices in section 11-D. The alpha testing summary is included in section 11-H.

Regression Testing
The objective of regression testing was to ensure that critical areas of the SoftBank II 25.1 system functioned as expected. Test cases that were assigned either a Critical Control Point level of 5 or 4 were executed. CCP level 5 functions are considered the most serious. This functionality has a direct impact on patients, and if it fails, this could result in the release of unsuitable blood to a patient. Level 4 CCP functionality includes areas of the system that display patient or unit information. The regression testing summaries are included in section 11-H.

Beta Testing
The objective of beta testing was to perform validation and verification testing in a user environment. Baylor Health Care System in Dallas, Texas, was the facility selected to beta test SoftBank II Version 25.1. The beta testing approach was similar to the alpha testing approach and users performed manual testing using test cases provided by SCC Soft Computer. The beta testing summary is included in section 11-H.

Conclusions Drawn from Testing
New functionality introduced in SoftBank II Version 25.1 was verified successfully during alpha testing. The results of regression testing demonstrated that safety critical functionality performed as expected. The beta testing confirmed that SoftBank II Version 25.1 could be utilized in a user environment. All failures were evaluated by a domain expert and either corrected or scheduled for future correction. A listing of unresolved anomalies is included in section 11-I.

Safety and Effectiveness Conclusion:
SoftBank II Version 25.1 was developed using the design controls incorporated in SCC's SDLC SOP 1011 procedure which is based on the Quality System Regulations.

The software device will perform as well as the predicate device as demonstrated by the alpha and beta testing. The testing assessment verifies that the device performs as designed, per the functional requirements, when utilized within its intended use.