SoftBank Version 25.6.1.0
Traditional 510(k) Summary

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Device Class: Class II

Trade name: SoftBank Version 25.6.1.0, marketed as SoftBank.web

Common name: Software, Blood Bank, Stand Alone

Classification name: Blood Establishment Computer Software (21CFR 864.9165, Product Code MMH)

Predicate Devices: SoftBank Version 25.5.0.0, (BK140128)

Device Description

SoftBank Version 25.6.1.0 was designed to enable the utilization of the current application with additional functionality including a web-based user interface. The functionality of the predicate device, SoftBank Version 25.5.0.0 (BK140128), is the foundation on which the added functionality was designed. All of the previous functionality of the SoftBank application is intact.

Intended Use

The SoftBank software application supports single and multi-site transfusion services in healthcare facilities. The software application is intended to be used by knowledgeable, trained medical and healthcare personnel to document, query, and view the integrated information regarding patients and products. All steps and events are captured in this decision support system, including quality control testing, complete test and transfusion history, transfusion management, inventory management, product distribution and final disposition. The system allows manual data entry and retrieval, as well as automated data exchange by interfacing to hospital information systems, blood bank instruments,

transfusion management systems and blood storage devices.

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 those risks in accordance with ISO 14971 Medical devices - Application of risk management to medical devices. Hazards are mitigated by identifying new requirements to reduce the hazard, provide appropriate warnings to the user, or adding warning statements to the product labeling.

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.

Comparison of Functional Characteristics to the Predicate Device

Areas of Comparison	SoftBank Version 25.6.1.0	SoftBank Version 25.5.0.0 (BK140128)
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.	✓	✓
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.	✓	✓
Allows products in inventory to be moved to remote blood storage devices.	✓	✓
Inventory of Product Label Formats		
Provides for Codabar and ISBT blood product labels.	✓	✓
Allows for receipt of ISBT labeled blood products.	✓	✓
Accommodates all required field specifications for ISBT.	✓	✓

Areas of Comparison	SoftBank Version 25.6.1.0	SoftBank Version 25.5.0.0 (BK140128)
Allows for expanded blood product extension code field to handle divided units per specifications.	✓	✓
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	✓	✓
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	✓	✓

Areas of Comparison	SoftBank Version 25.6.1.0	SoftBank Version 25.5.0.0 (BK140128)
ordered.		
Provides electronic determination of compatibility for remote allocation of compatible blood products.	✓	✓
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.	✓	✓
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.	✓	✓
Provides the ability to interface to remote blood storage devices.	✓	✓
Provides the ability to interface with Hospital Information Systems for the exchange of data	✓	✓

Areas of Comparison	SoftBank Version 25.6.1.0	SoftBank Version 25.5.0.0 (BK140128)
User Interfaces		
Provides a graphical user interface-SoftBank working in conjunction with SoftScape.	✓	✓
Provides a web based user interface-SoftBank works in conjunction with WebScape.	✓	
Provides user interface elements such as fonts, colors, component sizes and placement that can be customized for client preference.	✓	
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.	✓	✓

Comparison of Technological Characteristics to the Predicate Device

Areas of Comparison	SoftBank 25.6.1.0	SoftBank Version 25.5.0.0 (BK140128)
CPU	Intel Core i5 Quard-Core 3 GHz	2 core RISC processors
Memory (Ram)	32 GB	32 GB
Disk Space	1.2 TB	1.2 TB
Operating System	Linux 7.3	IBM AIX Version 5.1
Oracle Software	Oracle 12	Oracle 10.2
PC	Intel Core i5 Quad-Core 3 GHz (i5-3330) 4 GB RAM 500 GB HD 100 Mb/s network adapter 1920 x 1080 display Windows 10 Chrome 62.0+	Intel Core2 Duo 2GHz 2 GB RAM 64 GB HD 100 Mb/s network adapter 1024 x 768 256 colors display Windows XP SoftScape 1.3

Peripherals	**Bar Code Reader** – Scanner: Intermec SR30 Kit Linear Imager USB Cable (BB Scanner)	**Bar Code Reader** – Scanner: Intermec SR30 Kit Linear Imager USB Cable (BB Scanner)
	Dot Matrix Printer- Okidata ML 320 Dot Matrix Printer (80 Column) (transfusion slips)	**Dot Matrix Printer**- Okidata ML 320 Dot Matrix Printer (80 Column) (transfusion slips)
	Thermal Label Printer- (for ISBT labels)- ZEBRA Printer GX420T Direct Thermal Transfer Printer - (for BB: used for printing the crossmatch selection label)	**Thermal Label Printer**- (for ISBT labels)- ZEBRA Printer GX420T Direct Thermal Transfer Printer - (for BB: used for printing the crossmatch selection label)

We conclude that SoftBank Version 25.6.1.0 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.

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.

Regression Testing
The objective of regression testing was to ensure that critical areas of the SoftBank 25.6.1.0 system functioned as expected. Test cases that were assigned either a Critical Control Point (CCP) 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, could result in death or irreversible injury with permanent loss of function. CCP level 4 functions are considered to be areas of the system that impact patient or unit information, if a failure occurs permanent lessening of body function, disfigurement, or surgical intervention required for treatment could result.

Conclusions Drawn from Testing
New functionality introduced in SoftBank Version 25.6.1.0 was verified successfully during alpha testing. The results of regression testing demonstrated that safety critical functionality   performed as expected. All failures were evaluated by a domain expert and either corrected or   scheduled for future correction based upon risk.

Safety and Effectiveness Conclusion
SoftBank Version 25.6.1.0 was developed using the design controls incorporated in

SCC's Software Development Processes, which are based on the Quality System Regulations.

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