SOFTBANK II® VERSION 25

TRADITIONAL 510(K) SUMMARY

DATE

March 20, 2009

PROPRIETARY NAME

SoftBank II® Version 25

COMMON/USUAL NAME

Blood Establishment Software

CLASSIFICATION

Unclassified

There are no FDA performance standards promulgated for this device.

CONTACT INFORMATION

Laurie Sapp
SCC Soft Computer
SoftBank Product Manager
(727) 789-0100 ext. 4669
lauries@softcomputer.com

SCC Soft Computer 510(k) Summary

SCC Soft Computer is submitting SoftBank II® Version 25 as a Traditional 510(k) based on the number of enhancements that were made, not the severity of each individual enhancement. SCC Soft Computer's product SoftBank II® Version 23.2 (BK080020) is the predicate device.

We provided the Submission cover sheet in Tab 1 with the referenced Medical Device User Fee. The Device Labeling consisting of an Intended Use Statement, the SoftBank II® CD with labeling, SoftBank II® Version 25 User Manual, SoftBank II® brochures and Indications for Use are provided or referenced in Tab 5.

The Device Description is under Tab 6. The design documentation consisting of the Dataflow diagrams, Deployments and Sub System Diagrams and Process/Processor Diagrams are under Tab 6. The Hardware requirements and Deployment procedure are also in Tab 6.

Device Description

SoftBank II® Version 25 was designed to enable the utilization of the current application with additional functionality including expanded demographic fields, ability to handle multiple time zones, improved neonatal specimen handling, irradiator interface, interface to portable devices for bedside transfusion, and supply tracking. The functionality of the predicate device, SoftBank II® Version 23.2 (BK 080020), 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® Version 25 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 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 interpretation 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).

Predicate Device

SoftBank II® Version 25 enables the utilization of the current application with additional functionality including expanded demographic fields, ability to handle multiple time zones, improved neonatal specimen handling, irradiator interface, interface to portable devices for bedside transfusion, and supply tracking. SCC Soft Computer's product SoftBank II® Version 23.2 (BK080020) is the predicate device. A comparison of features and functionality is included in Tab 4 in a document titled **Predicate Device Comparison**. We determined that SoftBank II® Version 25 is substantially equivalent to the predicate device. The predicate device information is Tab 4.

Hazard Analysis

The new functionality was analyzed according to SCC Soft Computer's hazard analysis procedure during the design and development of the functionality. All hazards specifically associated with the enhancements and additional interfaces were analyzed independently. The hazard analysis summary report is located in Tab 8.

Design Control Activities Summary

SCC Soft Computer's activities to ensure 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 the addition of 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 perform a requirements traceability matrix. The traceability matrix for the new functionality along with the test cases is referenced in Tab 7 and can be found in a separate binder labeled **Hazard Analysis Traceability**. The verification and validation output documents are provided in Tab 7 along with the test cases and testing summaries and acceptance criteria. Regression testing for the entire product was also performed to demonstrate that the entire blood bank software still functioned correctly and as designed.

Verification & Validation

Change Testing

Change testing was identified by the traceability matrix. The traceability matrix in DOORS identified the new requirements and new test cases or exiting test cases that were impacted by the new requirements and or hazards. There were 875 test cases identified for change testing. There were 133 critical test cases with 2 failures and 742 non-critical test cases with 15 failures. The 2 critical test cases that failed were reviewed by product management and it was determined that the functionality was met but that there was a cosmetic display inconsistency. The 15 non-critical failures were reviewed by product management and deemed non-significant. The change testing summary is located in Tab 7. The change test cases, referenced in Tab 7, that test the enhancements can be found in a separate binder labeled **Change Testing Scripts and Run Results**.

Regression Testing

Automated regression testing was performed on SoftBank II® Version 25. Test cases are assigned a Criticality Control Point level of 5 (CCP 5 - most serious) if the functionality has a direct impact on patients.

If this functionality fails, this could result in the release of unsuitable blood to a patient. 146 CCP 5 test cases, that impact directly on patients, were run and there were 2 non-critical failures as well as one non-critical failure not related to SoftBank II®. The 3 non-critical failures were reviewed by product management and deemed non-significant. Of the 146 test cases 123 were deemed critical and 23 were non-critical. There were 100 CCP 4 test cases run. Level 4 CCP is defined as test cases that display patient or unit information. Of the 94 test cases, 33 were deemed critical and 61 were non-critical. There was one non-critical failure that was reviewed by product management and deemed non-significant. The regression testing summaries are included in Tab 7.

Beta testing

Beta testing of the enhancements to the existing functionality including expanded demographic fields, ability to handle multiple time zones, improved neonatal specimen handling, irradiator interface, interface to portable devices for bedside transfusion, and supply tracking was performed at four client locations. Beth Israel Deaconess Medical Center, Robert Wood Johnson University Hospital Hamilton, and MAYO clinic – Arizona were selected as beta clients because of their customization requests. Mobile Infirmary Medical Center was selected as a beta client because they are a current SoftBank II® user and would be able to evaluate the enhancements on the system. There were 360 test cases selected to test the enhancements made in SoftBank II® Version 25 that the beta clients were to receive. Each client would be allocated to run test cases that were applicable to their specific environment and workflow. There were 34 test cases assigned to beta clients that were not executed due to system setup, parameter settings, and/or workflow. The Beta testing summaries are included in Tab 7. The actual beta testing scripts, including the testing results, are located in separate binders labeled with each beta client's name.

Beth Israel Deaconess Medical Center received 49 test cases, 19 were critical and 30 were non-critical. The client executed 48 test cases. The client was not able to execute one critical test case due to a system parameter setting. All executed test cases were performed with no failures after corrections.

MAYO-Clinic-Arizona received 77 non-critical test cases. The client executed 70 test cases, 7 test cases were not tested due to system setup. All executed test cases were performed with no failures after corrections.

Mobile Infirmary Medical Center received 104 test cases, 30 were critical and 74 were non-critical. The client executed 97 test cases. The client was not able to execute 4 critical test cases, 3 due to their workflow and 1 due to system parameter setting. The client was not able to execute 4 non-critical test cases due to the client's workflow. All executed test cases were performed with no failures after corrections.

Robert Wood Johnson University Hospital Hamilton received 130 test cases, 29 test cases were critical and 101 were non-critical test cases. The client executed 111 test cases. The client was not able to execute 2 critical test cases due to their workflow. The client was not able to execute 12 non-critical test cases, 2 due to the client's workflow and 10 due to system parameter settings. All executed test cases were performed with no failures after corrections.

There are 126 non-critical unresolved anomalies remaining in SoftBank II® Version 25, listed in Tab 7.

ALL RECORDS ARE AVAILABLE FOR REVIEW UPON REQUEST.