

# SOFTBANK II VERSION 23.2

## SPECIAL 510(K) SUMMARY

### DATE

April 14, 2008

### PROPRIETARY NAME

SoftBank II Version 23.2

### 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](mailto:lauries@softcomputer.com)

### SCC Soft Computer 510(k) Summary

SCC Soft Computer is submitting SoftBank II Version 23.2 as a Special 510(k) that adds the capability to print ISBT blood product labels for modified blood products. SCC Soft Computer's product SoftBank II Version 23.1 with Database Management System Interface (BK 040048) is the predicate device.

We provide 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 23.2 User Manual, SoftBank II brochures and Indications For Use are provided or referenced in Tab 5.

The Device Description consisting of the SoftBank II Version 23.2 requirements and the SoftBCL Version 1 requirements are included 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 and Device Description are also in Tab 6.

## **Device Description**

SoftBank II Version 23.2 was designed to have the added capability to print ISBT compliant labels for modified blood products. The functionality of the predicate device, SoftBank II Version 23.1 with Database Management System Interface (BK 040048), is the foundation on which the added functionality of ISBT complaint label printing was designed. All of the previous functionality of the SoftBank application is intact.

## **Intended Use**

The SoftBank II Version 23.2 application is a decision support software device that requires knowledgeable user intervention to document certain steps and events in a transfusion service. The software documents the receipt of inventory from an outside source, multi-site inventory control, records the confirmatory testing on the units and allows for record keeping on component preparation for transfusion.

It records patient-related testing such as ABO/Rh and antibody screens, documents compatibility between patients and products, and records release of products for transfusion to recipients. The system supports documentation of compatibility by providing the ability to record crossmatch results. The system also allows for the electronic determination of compatibility while maintaining its decision support capability.

Warnings are provided to alert the user on various control points in the selection and issuance process, including locking of patient records when vital data can be changed. This function allows more than one user to access the record only in sub-options that do not allow change of critical patient information. The system records final disposition of a product to include documentation of transfusion to recipients, and provides the ability to perform a transfusion reaction workup in the presence of an adverse event.

The system allows the user to document receipt of reagents used in testing and record the test results for daily reagent quality control. The system also documents receipt of pharmaceutical products such as Rh Immune Globulin and albumin and records the assignment and issuance of these products to patients.

SoftBank II provides complete multi-facility workflow management and reporting including generation of management and inventory reports to assist the user in the supervisory role. SoftBank II provides the ability to interface with automated blood bank instruments allowing the transfer of results and interpretations from the instrument to SoftBank. It provides segment tracking for the use in centralized transfusion services to allow performance of compatibility testing to be performed in a single location and distribution of the blood product from a remote location. The system allows the user to search the database for all similar patients and link or unlink patients based on current information, alerting the user to previously documented requirements of linked patients. The system provides the option of electronic delivery of blood products files from the supplier when the files are properly formatted.

SoftBank II Version 23.2 was built on SoftBank II Version 23.1 with DMSI (predicate device) which incorporated the SoftScape user interface.

SoftBank II Version 23.2 incorporates the functionality of previous versions of SoftBank and adds the capability of printing ISBT compliant labels when modifying ISBT labeled blood products. Codabar products may be pooled with or without ISBT labeled products into ISBT labeled pooled products.

## **Predicate Device**

SCC Soft Computer is submitting SoftBank II Version 23.2 as a Special 510(k) that adds the capability to print ISBT blood product labels for modified blood products. SCC Soft Computer's product SoftBank II Version 23.1 with Database Management System Interface (BK 040048) 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 23.2 is substantially equivalent to the predicate device and does not change the intended use of the product.

## **Hazard Analysis**

The new functionality was analyzed according to SCC Soft Computer's hazard analysis procedure during the design and development of the functionality and no new hazards were identified.

## **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 perform a requirements traceability matrix. The traceability matrix for the new functionality along with the test cases is provided in Tab 7 and the requirements in Tab 6. The verification and validation output documents are provided in Tab 7 along with the test cases, 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 existing test cases that were impacted by the new requirements and or hazards. There were 104 test cases identified for change testing. There were 40 critical test cases with one failure and 64 non-critical test cases with 4 failures. The critical test case that failed was reviewed by product management and it was determined that the functionality was met but there was a cosmetic display inconsistency. The 4 non-critical failures were reviewed by product management and deemed non significant.

Automated regression testing was performed on SoftBank II Version 23.2. 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. 147 CCP 5 test cases, that impact directly on patients, were run and there were no failures. There were 96 CCP level 4 test cases run. Level 4 CCP is defined as test cases that display patient or unit information. Of the 96 test cases, 34 were deemed critical and 62 were non-critical. The 34 critical test cases passed and 3 of the 62 non-critical test cases failed. The 3 non-critical failures were reviewed by product management and deemed non significant.

### ***Beta testing***

Beta testing of the ISBT labeling functionality was performed at two client locations. The clients were selected due to Hendricks Medical Center using the Digi-Trax Hema Trax server printing system and Underwood Memorial Hospital not using Digi-Trax Hema Trax server, instead printing labels using a 300dpi printer. Both clients are Codabar based, drawing or receiving Codabar labeled units, with a need to print ISBT labels for products that are modified (changed or pooled). The beta clients were to receive 115 test cases selected to test ISBT labeling functionality, the new changes, and fixes in version 23.2, from the predicate software (BK040048). The number of test cases the client received was larger than change testing because the client was required to run test cases from different options, print different quadrants of a label, and print complete labels. Each client executed only those test cases that were applicable to their specific environment and workflow therefore the number of test cases executed is different for each client. However, all test cases that involved creation of ISBT labels for modified products were executed.

Underwood received one additional test case (total 116) as part of the corrected build of SoftBank II Version 23.2.0.0.7 and SoftBCL Version 1.0.0.0.10. 46 critical and 40 non-critical test cases were performed with no failures after corrections.

Hendricks Medical Center executed 51 critical test cases with 1 failure and 48 non-critical test cases with 1 failure. Both failures were evaluated by the product management team. The client decided that the functionality in the critical test case “failed” because they changed the expected result to match their workflow; thereby failing the step and the test case. The program, in fact, produced the expected result as defined in the original test case. Client needs associated with the failure will be addressed in a later version of SoftBank II. The non-critical test case failure is being corrected in a patch that the client will receive.

There are 40 non-critical unresolved anomalies remaining in SoftBank II Version 23.2, listed in Tab 7.

**ALL RECORDS ARE AVAILABLE FOR REVIEW UPON REQUEST.**