# 510 (k) SUMMARY

# SOFTBANK II VERSION 23.0 with SOFTSCAPE 510(K) SUMMARY

### DATE

March 31, 2004

### PROPRIETARY NAME

SoftBank II Version 23.0 with SoftScape

### COMMON/USUAL NAME

Blood Establishment Software

### CLASSIFICATION

There is currently no classification for this device.

**There are no FDA performance standards promulgated for this device.**

### CONTACT INFORMATION

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### DEVICE DESCRIPTION

SoftBank II version 23.0 application with the SoftScape User Interface provides the user with a graphical presentation of SoftBank II version 23.0's fields and screens without changing the business logic in SoftBank II version 23.0, the predicate device. SoftBank II version 23.0 with SoftScape enables the user to navigate through the system via a PC mouse or the keyboard, and provides user friendly drop down menus within the existing ASCII fields for data entry (such as calendars for entry of dates in fields). The following documentation will describe the SoftScape User Interface, SoftBank II version 23.0 (the application), and SoftBank II version 23.0 with SoftScape User Interface. Since the business logic has not changed, the focus of testing and validation has been to verify the performance of SoftBank II version 23.0 with SoftScape, appropriate display of the legacy ASCII application and ability to navigate throughout the system easily and in a timely manner.

The SoftScape User Interface is a PC based application designed to allow the user to access ASCII applications via a Windows™-based user interface. This is a method of accessing the legacy ASCII SoftBank II version 23.0 application, which is a decision support software device requiring knowledgeable user intervention by competent medical personnel to document certain activities or steps and events in a transfusion service. Once launched, SoftScape presents a menu of accessible applications and environments. Selecting the application and environment from this menu is equivalent to entering into UNIX with a designated login name. SoftScape was designed to be a user-friendly means of navigation through the SoftBank II version 23.0 ASCII application. Analysis of SoftScape consists of verification of its ability to accurately perform when used with the SoftBank II version 23.0 application.

SoftScape was the user interface library chosen to supply the windows, fields, and function keys utilized in SoftBank II.

The SoftBank II system was designed in a modular format consisting of seven functional subsystems that support the various activities in a transfusion service. These subsystems include the following:

A   Patient
B   Inventory
C   Product Order Service
D   Results
E   Management
F   Setup Files
G   Donor

The architectural design of the SoftBank II system incorporates each of the individual subsystems into one of six options on a main menu.

## INTENDED USE

The SoftBank II Version 23 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 version 23 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 transfer of blood product delivery files from the supplier when properly formatted.

The SoftScape User Interface is designed to be a Windows™-like user interface for the legacy ASCII application. SoftScape is used in conjunction with SoftBank II version 23.0, a decision support software system that requires knowledgeable user intervention to document certain steps and events in a transfusion service. The incorporation of SoftScape does not change the business logic of the SoftBank application.

## SUBSTANTIAL EQUIVALENCE

SoftBank II Version 23.0 with SoftScape was developed utilizing the predicate device SoftBank II Version 23.0 as a baseline for the addition of the user interface to the product. The technological characteristics of the SoftBank II Version 23.0 with SoftScape are the same as the predicate. There were no changes to technology, business logic or software/hardware architecture in the new version. The submitted software device is substantially equivalent in functionality and intended use to the predicate developed by SCC/SoftComputer. Both systems are decision support software devices that require knowledgeable user intervention to document steps and events in a transfusion service.

Use of the new user interface with SoftBank II version 23.0 was analyzed for hazards when applicable, tested at the unit/integration, system (alpha) and acceptance (beta) test levels. The results of the testing activities met the acceptance criteria. The verification activities concluded no new safety or effectiveness issues were raised with the implementation of the new software user interface.