SOFTBANK II VERSION 23.1 WITH DATABASE MANAGEMENT SYSTEM INTERFACE

ABBREVIATED 510(K) SUMMARY

DATE

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PROPRIETARY NAME

SoftBank II v 23.1 Database Management System Interface (DMSI)

COMMON/USUAL NAME

Blood Establishment Computer Software

CLASSIFICATION

Unclassified

There are no FDA performance standards promulgated for this device.

CONTACT INFORMATION

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DEVICE DESCRIPTION

SoftBank II version 23.1 with DMSI is a SoftBank application that allows the utilization of current application calls to access other databases such as Oracle™ through the Dora library. DMSI is a set of functions used by the Application Program Interface (API) of the RAIMA Database Manager runtime library (dbVista library). The original implementation of the API is the dbVista library, which is used by all SoftBank versions. SoftBank II version 23.1 with DMSI enables the application to use a different implementation of the DMSI through the Dora library without changing the SoftBank 23.0 source code and is part of the SoftBank application, not a stand-alone interface. The Dora library uses the Oracle database to store data; the API calls are translated into SQL statements, which are then executed in the Oracle Database Management System, and the results are returned to the SoftBank application.

SoftBank II Version 23.0 was designed to be 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. It was designed to be a sophisticated but user-friendly system that can be used as a standalone system or as an integrated part of SCC' s clinical information systems.

INTENDED USE

The SoftBank II Version 23.1 with DMSI 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 crossmatching 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 23.0 provides an instrument listener with automated blood bank instruments allowing the transfer of results and interpretations from the instrument to SoftBank II to be accepted by the user. It provides segment tracking for use in centralized transfusion services to allow performance of compatibility testing to be performed in a central 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 invoice files from a supplier in a properly formatted file to SoftBank II.

DMSI with SoftBank II version 23.1 is a SoftBank application that allows the utilization of current application calls to access other databases such as Oracle™ through the Dora library.

SOFTBANK II VERSION 23.1 WITH DMSI DOES NOT CHANGE THE INTENDED USE OF SOFTBANK II VERSION 23.0.

SUBSTANTIAL EQUIVALENCE

SoftBank II Version 23.1 with DMSI was developed utilizing the predicate device SoftBank II Version 23.0 The technological characteristics of the DMSI with SoftBank II version 23.1 are the same as the predicate. There were no changes to technology or software/hardware architecture in the interaction with DMSI. The SoftBank II version 23.1 interaction with DMSI is substantially equivalent in functionality and intended use to the predicate developed by SCC/Soft Computer in that no changes were made to SoftBank II version 23.0. No new functional requirements were added. Both systems are decision support software devices that require knowledgeable user intervention to document steps and events in a transfusion service.

ALL RECORDS ARE AVAILABLE FOR REVIEW UPON REQUEST.