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SOFTDONOR VERSION 4.3 with SOFTSCAPE 510(K) SUMMARY

DATE

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PROPRIETARY NAME

SoftDonor Version 4.3 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

SoftDonor version 4.3 application with the SoftScape User Interface provides the user with a graphical presentation of SoftDonor version 4.3's fields and screens without changing the business logic in SoftDonor version 4.3. The new graphical interface 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, SoftDonor version 4.3 (the application) and SoftDonor version 4.3 with SoftScape User Interface. The predicate devices, SoftDonor version 4.1 and SoftBank II version 23 with SoftScape, have been used to prove that no major functionality changes have been introduced to the application that affect safety and efficacy and that the same user interface used by SoftBank v 23 with SoftScape has already been cleared. Since the business logic has not changed, the focus of testing and validation has been to verify the performance, the display of the legacy ASCII application, and navigation of SoftDonor version 4.3 with SoftScape.

The SoftScape User Interface is a PC based application designed to allow the user to access ASCII applications while providing a graphical user interface appearance. This is a method of accessing the legacy ASCII SoftDonor version 4.3 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 donor center. 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 SoftDonor version 4.3 ASCII application. Analysis of SoftScape consisted of verification of its ability to accurately perform when used with the SoftDonor version 4.3 application.

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

The SoftDonor system was designed in a modular format consisting of seven functional subsystems that support the various activities in a donor center. These subsystems include the following:

- A Donor
- B Visits
- C Production
- D Tests
- E Inventory
- F Setup
- G Management

The architectural design of the SoftDonor system incorporates each of the individual subsystems into one of seven options on a main menu; Donor Demographics, Registration, Donor Screening, Testing, Component, Processing, Labeling, Shipping/Receiving, and Management Reports.

INTENDED USE

SoftDonor is intended to be a decision support system used by knowledgeable users to document steps in the manufacture of blood and blood components or for the maintenance of that data which blood center personnel use in making decisions regarding the suitability/deferral of donors and the release of blood or blood components for transfusion purposes or for further manufacture. It will support the following functionality:

1. The registration of suitable donors in multiple locations with real time evaluation of eligibility from registration through phlebotomy
2. The automatic or manual deferral of donors based on history review, donation interval based on last procedure, inappropriate responses to donor history questions, results of donor physical exams and transfusion transmitted disease test results.
3. Documentation of test results for the donor and for the donated unit
4. Documentation of ABO & Rh results
5. Antibody screen results

6. Transfusion transmitted disease test results
7. Antigen tests results
8. Results of donor history questions
9. Results of donor physical tests
10. The labeling and distribution of blood and blood components and management of inventory including recall of inventory
11. Quarantine or removal from production of components that do not meet prescribed production timeframes or guidelines
12. Quarantine or removal of components that have positive test results
13. The coordination and linking of autologous and directed donations with the appropriate recipient
14. The documentation of current Good Manufacturing Practices (cGMP) in the manufacture of blood components
15. The system may be configured for infectious disease testing to be done in-house or by external organizations
16. The system supports the search and retrieval of eligible donors by various criteria including, ABO, Rh, HLA and antigen profiles

The use of the SoftScape User Interface with SoftDonor Version 4.3 provides a graphical presentation layer to the legacy ASCII application. It allows the user to navigate through the application via a mouse or keyboard, and provides improved data entry into fields by means of drop down menus for entry selection, such as calendars for entry of dates in fields. SoftScape is used in conjunction with SoftDonor Version 4.3 (ASCII application), a decision support system used by knowledgeable users to document steps in the manufacture of blood and blood components or for the maintenance of that data which blood center personnel use in making decisions regarding the suitability/deferral of donors and the release of blood or blood components for transfusion purposes or for further manufacture.

The incorporation of SoftScape does not change the functionality or business logic of the SoftDonor application.

The following functions are not supported by SoftDonor Version 4.3:

- Mobile functionality for delayed registration of donors on laptops using a copy of the database with either real time checking of deferral status of presenting donor or checking of donor deferral status when donor registration record is uploaded to the host computer is not currently available. However, mobile registration of donors on line and in real time can be accomplished by a laptop using a terminal emulator and an aircard modem (or other live network connection).
- SoftDonor does not perform HLA compatibility of donors and recipients

- SoftDonor does not perform patient compatibility
- SoftDonor does not perform donor credit system accounting
- SoftDonor does not document or store donor picture identification cards or donor signature verification
- SoftDonor does not perform manpower and equipment scheduling for mobiles or fixed sites to measure projected donors to be drawn using a scheduling module
- SoftDonor does not prevent the use of instruments that are outside of quality control parameters in the component production process

SUBSTANTIAL EQUIVALENCE

SoftDonor Version 4.3 with SoftScape was developed utilizing the predicate devices SoftDonor Version 4.1 and SoftBank v23 with SoftScape. The submitted software device is substantially equivalent in functionality and intended use to the predicate, SoftDonor v4.1 (BK020006), developed by SCC Soft Computer. The technological characteristics of the SoftDonor Version 4.3 with SoftScape are the same as the predicate. There were no changes to technology, business logic or software/hardware architecture in the new version. In addition, the submitted software device is substantially equivalent to predicate, SoftBank v23 with SoftScape (BK040028), in regards to the introduction of the new graphical presentation layer in submitted software SoftDonor Version 4.3 with SoftScape.

Use of the new user interface with SoftDonor version 4.3 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.