

510(k) SUMMARY

Proprietary Name

SoftDonor Version 4.1

Common/Usual Name

Blood Establishment software

Classification

81MMH as assigned by FDA.

Device Description

SoftDonor Version 4.1 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 donor center. It was designed to be a sophisticated system that can be used as a standalone system or as an integrated part of SCC's clinical information systems.

The system was designed to operate on the Unix operating system on the IBM RISC 6000 platforms. The C language, the standard coding language of the Unix operating system, was chosen for its portability between different operating systems. Unix is considered a multi-user system with capabilities of utilizing one CPU and connecting to many "dummy" terminals. There is also the option of connecting to a network and running through a PC.

SoftDonor utilizes the db_Vista™ database management system. It was chosen at the time because it was one of the best database management systems utilizing libraries in the C language. It is an extremely fast database because of its ability to "link" between records. The database structure combines relational elements with network-like direct links between specific records. The database also provides a transaction mechanism that prevents database inconsistencies by requiring that all associated records be updated. This provides a more "secure" database by simply not updating records if an inconsistency is found.

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

- 1 Donor
- 2 Visits
- 3 Production
- 4 Tests
- 5 Inventory
- 6 Setup
- 7 Management

The architectural design of the SoftDonor system incorporates each of the individual subsystems into one of seven options on a main menu.

Intended Use

The SoftDonor Version 4.1 application is a decision support software device that requires knowledgeable user intervention to document certain steps and events 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 system supports the registration of suitable donors in multiple locations with real time evaluation of eligibility from registration through phlebotomy. The system provides for 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. Test results for the donor and for the donated unit are documented, including documentation of ABO and Rh results, antibody screen results, transfusion transmitted disease test results, antigen tests results, results of donor history questions, results of donor physical tests, the labeling and distribution of blood and blood components, and management of inventory, including recall of inventory. The system supports quarantine or removal from production of components that do not meet prescribed production timeframes or guidelines and quarantine or removal of components that have positive test results. The system coordinates and links autologous and directed donations with the appropriate recipient. The system promotes the documentation of current Good Manufacturing Practices (cGMP) in the manufacture of blood components. The system may be configured for infectious disease testing to be done in-house or by external organizations. The system supports the search and retrieval of eligible donors by various criteria including, ABO, Rh, HLA, and antigen profiles.

Substantial Equivalence

SoftDonor Version 4.1 was developed utilizing the predicate device SoftBank II Version 19.1 (BK 960033) and Version 21.2 (BK000040) for hardware, operating system, security, and programming language. The technological characteristics of the SoftBank II Version 19.1 and Version 21.2 are the same as SoftDonor Version 4.1. The technology or software/hardware architecture in SoftDonor Version 4.1 is similar to SoftBank II. The submitted software device is substantially equivalent in functionality and intended use to the specified pre-amendment predicate devices. SoftDonor Version 4.1 is a decision support software device that requires knowledgeable user intervention to document steps and events in a donor center.

Functional requirements were analyzed for hazards when applicable and 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 safety or effectiveness issues were raised with the implementation of the software requirements.