SoftDonor Version 4.5.5
Traditional 510(k) Summary

Assigned STN: BK210607

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Device Class: Unclassified

Device Name:

Proprietary Name: SoftDonor Version 4.5.5 marketed as SoftDonor.web
Classification: Blood Establishment Computer Software (21 CFR 864.9165, Product Code MMH)

Predicate Devices: SoftDonor Version 4.5.0, (BK080069)

Device Description:

SoftDonor Version 4.5.5 was designed to enable the utilization of the current application with additional functionality including a web based graphical user interface as well as the option for an online donor history questionnaire. The functionality of the predicate device, SoftDonor Version 4.5.0 (BK080069), is the foundation on which the added functionality was designed. All of the previous functionality and logic of the SoftDonor application is intact.

Intended Use:

The SoftDonor software application supports single and multi-site blood center facilities. The software application is intended to be used by knowledgeable, trained medical personnel to document, query, and view integrated information regarding donors and products. All steps and events are captured in this decision support system including the manufacture of blood and blood components, suitability/deferral of donors, and the release of products for transfusion purposes or for further manufacturing. The system supports the use of both user or donor administered history questionnaire functionality along with additional system logic to determine donor eligibility which includes testing as well as donor health screening. The system allows manual data entry and retrieval, as well as automated data exchange by interfacing to laboratory information systems, transfusion service systems, testing facilities and recruitment systems.

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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) or Patient Risk Assessment. 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 create a requirements traceability matrix.

Comparison of Functional Characteristics of SoftDonor Version 4.5.5 to the Predicate Devices SoftDonor Version 4.5.0, (BK080069):

Areas of Comparison **Functional Characteristics of SoftDonor**	**Submitted Device SoftDonor Version 4.5.5**	**Predicate Device SoftDonor Version 4.5.0 (BK080069)**
Donor		
Enter and maintain donor demographic information, search for related or similar records, and merge when appropriate.	✓	✓
Establish recruitment criteria, send letters, and display appointments	✓	✓
Construct and maintain a Deferral Registry.	✓	✓
Recall units based on deferrals.	✓	✓
Document antigens, antibodies, characteristics, donor clubs, historical donations, and comments	✓	✓
View recruitment and other statistical reports	✓	✓
Visits		
Review the history of previous visits.	✓	✓
Provides the ability for donor center personnel to administer and evaluate a Donor History Questionnaire for Donor eligibility.	✓	✓
Allow the completion of the Donor History Questionnaire to done by the donor securely online prior to the donor center visit	✓	
Ability to enter and evaluate results of a physical examination.	✓	✓
Record phlebotomy information, including supply lot numbers and expiration dates.	✓	✓
Provides CUE (Confidential Unit Exclusion) Ballot process	✓	✓
Manage test orders (enter/cancel)	✓	✓

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Areas of Comparison **Functional Characteristics of SoftDonor**	**Submitted Device SoftDonor Version 4.5.5**	**Predicate Device SoftDonor Version 4.5.0 (BK080069)**
Maintain the Patient Database for autologous, directed, designated, dedicated, and therapeutic donations, as well as units drawn for research purposes.	✓	✓
Set up sequences of acceptable Donation Numbers for the facility	✓	✓
Production		
Provides component production processes including the documentation of each step in the process	✓	✓
Maintain inventories of production supplies and containers.	✓	✓
Provides the ability to recall units according to supplies or containers used.	✓	✓
Monitor product quality control.	✓	✓
Initiate production orders and track them to completion.	✓	✓
Generate production reports.	✓	✓
Testing		
Management of donor testing results	✓	✓
Provides the ability to define testing algorithms order required repeat tests and confirmatory tests	✓	✓
Allow defined algorithms to defer donors, format donor notification letters, quarantine/discard components and set donor monitoring characteristics.	✓	✓
Inventory		
Verification of component labels and release of products based on logic labels and release of exceptions.	✓	✓
Receive, ship, transfer, or return blood units and blood products either singly or in batches.	✓	✓
Edit data on a blood unit such as antigens, antibodies, attributes, actions performed, labeling requirements, and comments.	✓	✓
Recall units according to Donation Number and Donation Status Code.	✓	✓
Manually enter a physical inventory and reconcile it to the electronic inventory in the database	✓	✓
ISBT Labels		
Provides ISBT label generation during component production	✓	✓
Allow for label verification during component labeling.	✓	✓
Provide the ability to generate ISBT donation numbers, intended recipient labels, and CMV negative labels can be generated	✓	✓
Interfaces		

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Areas of Comparison Functional Characteristics of SoftDonor	**Submitted Device SoftDonor Version 4.5.5**	**Predicate Device SoftDonor Version 4.5.0 (BK080069)**
Electronic File Transfer (electronic invoice) transfer of product inventory to a transfusion service.	✓	✓
Laboratory Information system for testing results	✓	✓
Donor recruitment system	✓	
User Interfaces		
SoftScape User Interface SoftDonor works in conjunction with SoftScape to provide a graphical user interface.	✓	✓
Web User Interface SoftDonor works in conjunction with WebScape to provide a web based graphical user interface	✓	
Provides user interface elements such as fonts, colors, component sizes and placement that can be customized for client preference.	✓	

Comparison of Technological Characteristics of SoftDonor Version 4.5.5 to Predicate Device to SoftDonor Version 4.5.0:

Areas of Comparison Technical Characteristics of SoftDonor	**Submitted Device SoftDonor Version 4.5.5**	**Predicate Device SoftDonor Version 4.5.0 (BK080069)**
CPU	Intel Core i5 Quard-Core 3 GHz	IBM RS/6000 Model 150
Memory (Ram)	32 GB	1 GB
Disk Space	1.2 TB	9.1 GB
Operating System	Linux 7.3	IBM AIX Version 5.1
Oracle Software	Oracle 12	
PC	Intel Core i5 Quad-Core 3 GHz (i5-3330) 4 GB RAM 500 GB HD 100 Mb/s network adapter 1920 x 1080 display Windows 10 Chrome 62.0+	Pentium II 1GHz 512 GB RAM 5.0 GB HD 100 Mb/s network adapter 1024 x 768 256 colors display Windows NT or higher SoftScape 1.0

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Peripherals	**Bar Code Reader** – Scanner: Intermec SR30 Kit Linear Imager USB Cable (BB Scanner) **Dot Matrix Printer**- Okidata ML 320 Dot Matrix Printer **Thermal Label Printer**- (for Blood Bag labels) Zebra S600 **Label Printer**-(For ISBT labels) using ZPL II that prints 300 DPI, Zebra Z4M	**Bar Code Reader** – Scanner: Intermec Scan Plus 1800 **Dot Matrix Printer**- OKI Microline 320 turbo **Thermal Label Printer**- (for Blood Bag labels) Zebra S600 **Label Printer**-(For ISBT labels) using ZPL II that prints 300 DPI, Zebra Z4M

We conclude that SoftDonor Version 4.5.5 employs the same or very similar types of technological characteristics as the predicate device including computer technology, hardware, computer operating system, database and related software.

Alpha Testing
The objective of alpha testing was to ensure the system had met its intended use and implementation of all new requirements was successful. Software requirements, corresponding test cases, and any related hazards were linked and can be viewed in the Traceability Matrices.

Regression Testing
The objective of regression testing was to ensure that critical areas of the SoftDonor 4.5.5 system functioned as expected. Test cases that were assigned either a Critical Control Point level of 5 or 4 were executed. CCP level 5 functions are considered the most serious. This functionality has a direct impact on patients, and if it fails, could result in death or irreversible injury with permanent loss of function. CCP level 4 functions are considered to be areas of the system that impact patient or unit information, if a failure occurs permanent lessening of body function, disfigurement, or surgical intervention required for treatment could result.

Conclusions Drawn from Testing
New functionality introduced in SoftDonor Version 4.5.5 was verified successfully during alpha testing. The results of regression testing demonstrated that safety critical functionality performed as expected. All failures were evaluated by a domain expert and either corrected or scheduled for future correction.

Safety and Effectiveness Conclusion:
SoftBank Version 4.5.5 was developed using the design controls incorporated in SCC's development procedures which is based on the Quality System Regulations.

The software device will perform as well as the predicate device as demonstrated by the alpha

testing. The testing assessment verifies that the device performs as designed, per the functional requirements, when utilized within its intended use.