

510(k) SUMMARY (BK180246)

Manufacturer Submitting 510(k):

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Name of Device:

Trade Name: Blood Bank Information Management System (BBIMS) v2.06.00
Classification Name: Blood Establishment Computer Software and Accessories
Device Class: Class II as of June 18, 2018; Previously Unclassified
Product Code: MMH
Panel: Hematology
Regulation Number: 21 CFR § 864.9165

Device Description:

BBIMS 2.06.00, with its Automated Questionnaire System (AQS) component, is a full service Blood Bank Information Management System that includes the following features:

- Automated Questionnaire System (AQS)
- Component Preparation & Maintenance
- Component Testing & Labeling
- Crossmatch & Consultation
- Donation/Unit Entry and Maintenance
- Product Inventory
- Product Ordering/Shipping
- Billing
- Donor Recruiting
- Record Auditing
- System Administration
- Application Express Reporting (APEX)

Intended Use:

Blood Bank Information Management System (BBIMS) v2.06.00 is a Blood Establishment Computer Software that is intended for use by trained healthcare professionals for the following blood manufacturing activities:

- Self-administered health history questionnaire to determine donor eligibility using web or mobile operating system technology
- Staff entered physical to determine donor eligibility
- Provide information data regarding the suitability of a donor making a donation
- Defer donors when they are prohibited from making a donation
- Store patient information during the manual crossmatch / consultation process
- Store and review test results for all units processed at a blood center, either through manual entry and/or instrument interfaces
- Label components based on Codabar and ISBT standards
- Ability to pool products (i.e., platelets, cryoprecipitate) into single components
- Interfaces with LifeTrak and Vista

Substantial Equivalence:

Device #1: Blood Bank Information Management System (BBIMS) v2.06.00 manufactured by Carter BloodCare is substantially equivalent to BBIMS 2.05.01 (BK090079) manufactured by Duley, Hopkins and Associates that was cleared by FDA on January 13, 2010. Carter BloodCare acquired BBIMS on September 23, 2017.

Device #2: AQS Mobile App manufactured by Carter BloodCare is substantially equivalent to Donor-ID 3.2 (integrated with iniCASI App iOS technology, optional) (BK150279) that is also a mobile app used by potential blood donors. Both systems include self-administered health history questionnaires using mobile operating system technology that produce barcodes to utilize during donor lookup.

Comparison to Cleared Device #1 (BBIMS 2.05.1)

Parameter/Character	Subject Device BBIMS 2.06.00	Predicate Device #1 BBIMS 2.05.1 BK090079
Intended Use	Same as predicate device	Self-administered health history questionnaire to determine donor eligibility
	Same as predicate device	Staff entered physical to determine donor eligibility
	Same as predicate device	Provide information data regarding the suitability of a donor making a donation
	Same as predicate device	Defer donors when they are prohibited from making a donation
	Same as predicate device	Store patient information during the manual crossmatch / consultation process
	Same as predicate device	Store and review test results for all units processed at a blood center, either through manual entry and/or instrument interfaces
	Same as predicate device	Label components based on Codabar and ISBT standards
	Same as predicate device	Ability to pool products (i.e., platelets, cryoprecipitate) into single components
Target Population	Same as predicate device	Trained healthcare professionals performing blood manufacturing activities:
	Same as predicate device	Donors completing the health history questionnaire
Browsers supported (for use with AQS Web Questionnaire only)	Internet Explorer 11 Safari 11 Firefox 60 Chrome 65	N/A
Mobile device operating systems supported (for use with AQS Mobile Questionnaire only)	Apple iOS 11 Android 7	N/A

Parameter/Character	Subject Device BBIMS 2.06.00	Predicate Device #1 BBIMS 2.05.1 BK090079
Remote Site Web Server	Microsoft Windows Server 2012 R2 Microsoft SQL Server 2012 Express IIS .Net API Framework Solar Winds SCP/SFTP Server v1.0.4.9	N/A
Browsers supported	Internet Explorer 11	Internet Explorer 7
Programming Language	Oracle Forms and Reports 12.2.1 Oracle WebLogic 12.2.1.1	Oracle Forms and Reports 10g, SQL and PL/SQL
Database	Oracle Relational Database 12.1.0.2	Oracle relational database Configuration 1 - 10g 10.1.0 Configuration 2 – 10g 10.2.1
Server OS	Oracle Enterprise Linux Server 6.7	Configuration 1 Sun Solaris 10 (database) Windows 2003 Server (application server) Configuration 2 Oracle Enterprise Linux R4u6 (database and application server)
Client OS	MS Windows 7 MS Windows 10	Microsoft Windows XP Professional
Input	Barcode Scanner Keyboard Blood Grouping Equipment Vista	Barcode Scanner Keyboard Blood Grouping Equipment
Administration Table	Same as predicate device	Allows user with security authorization to add, update or outdate data
	Same as predicate device	Provides hard-copy listing of each table and contents.
	Same as predicate device	Contains administrative functions for the maintenance of tests, products, services and providers
Data Backup and Restore	Same as predicate device	Data archival and retrieval via system level backups
Access Security	Same as predicate device	Manages user ID and password combinations
Audit Trail	Same as predicate device	Comprehensive history of all changes to blood data. Data accessible for review via blood product history report

COMPARISON OF AQS MOBILE APP TO CLEARED DEVICE #2 (Donor-ID 3.2 [integrated with iniCASI App iOS technology, optional])

Parameter/Character	Subject Device BBIMS 2.06.00 AQS Mobile App	Predicate Device #2 Donor-ID 3.2 iCASI App BK150279
Intended Use	Same as predicate device	Provide the donor with the opportunity to read and respond to the health history questions using an external mobile device on the collection day.
	Same as predicate device	Produce barcodes that are used upon presentation by the specific donor at the collection site to input the data provided by the donor and to confirm the date.
Target Population	Same as predicate device	Trained healthcare professionals performing blood manufacturing activities:
	Same as predicate device	Donors completing the health history questionnaire
Mobile device operating systems supported (for use with AQS Mobile Questionnaire only)	Apple iOS 11 Android 7	Apple iOS
Technological Characteristics	The technological characteristics are identical or similar to those of the predicate device. No new safety or effectiveness issues are introduced.	Mobile application that runs on a mobile device and <ul style="list-style-type: none"> • Uses standard system log-on and security features • Has a graphical user interface and relational database • Allows the donor to read and respond to the health history questions Generates a barcode that can be printed, emailed or scanned directly from a smart phone.

Comparison Summary:

BBIMS v2.06.00 and both predicates are Blood Establishment Computer Software intended for use by trained blood bank staff with a self-administered questionnaire intended to be used by donors. BBIMS v2.06.00 has the same intended use and technological characteristics in regard to design, function and application as the corresponding parts of the referenced predicated devices. Testing for BBIMS 2.06.00 verified the system is safe and effective, and performs as well or better than the predicate devices when utilized within its intended use.

Performance Data (Non-clinical and/or Clinical):

Verification and validation testing was performed at the unit, integration, and functional/system levels including verification testing of program packages and risk control measures. Test case matrices were developed using established procedures for software development.

Performance bench testing was performed by trained blood center staff and verified the application exceeded expectations and system requirements.

Carter BloodCare ensures that all safety critical items have been thoroughly tested and can demonstrate that all methods of control for intended use and general implementation hazards have been tested.