

510(k) Summary

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Submitter: Arc-One Solutions, LLC
7901 RIVIERA BLVD.
MIRAMAR, FLORIDA 33023
UNITED STATES

Official Correspondent: Jared McDonley
Director, Regulatory Affairs and Quality Systems
Office: 754-837-8835

Trade Name: RSA
Classification Name: Automated Blood Grouping and Antibody Test System
Common Name: Blood Establishment Computer Software
Product Code: MMH
Regulation Number: 21CFR 864.9175

Predicate Device:

Device Classification Name: Automated Blood Grouping and Antibody Test System
510(k) Number: BK180246
Device Name: BBIMS Version 2.06.00
Original Applicant: Carter BloodCare
Product Code: MMH
Regulation Number: 21CFR 864.9165
Decision Date: November 1, 2019
Decision: Substantial equivalent (SE)
Type: Traditional

Device Description:

RSA is a stand-alone blood establishment computer software application (BECS) that provides for management controls and information services that have been designed to assist personnel in the operation of a blood center. These controls include:

- Donor eligibility
- Donation entry and maintenance
- Component preparation and maintenance
- Component testing and labeling
- Product inventory
- Reference laboratory management

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Indications for Use:

Intended Use for Predicate Device: BBIMS is intended for use by trained healthcare professionals responsible for the safe collection, preparation, and distribution of blood products in the following ways:

- Self-Administered health history questionnaire to determine donor eligibility
- Staff entered physical to determine donor eligibility
- Provide information 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, both through manual entry and/or instrument interfaces
- Record information about the preparation and maintenance of blood products
- Label components based on Codabar and ISBT standards
- Maintain manufactured and blood product inventories by blood type and product type
- Maintain historical records of all donations made by a donor
- Store component information from products received from other facilities
- Maintain a product history from time received until final disposition
- Perform quality assurance checks and maintain quality assurance records

Intended Use for RSA: The RSA system is a computerized system intended to be used by trained personnel to aid in and document the donation, manufacture and distribution of blood products. The system is intended to be “paperless”, i.e. it supports self-administered health history and complete documentation of the determination of eligibility, physical exam and phlebotomy of blood donors, and aids in the manufacture, labeling and shipment of blood and blood products. Each module communicates with a single database and interface with third party systems through standard network connections. The system is compatible with wired or wireless networks.

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Device Comparison Table:

	Subject Device RSA 2.0	Predicate BBIMS Version 2.06.00 BK180246
Application Languages	JAVA 1.5, (b) (4) 3 & 4, PL/SQL (provided in Oracle 12c)	Oracle Forms and Reports 12.2.1 Oracle WebLogic 2.2.1.1
Database	Oracle Enterprise Edition Ver. 12C	Oracle relational database 12.1.0.2
Browsers	Internet Explorer 11	Internet Explorer 11
Operating System	Server: Oracle Enterprise Linux Version 6.4	Server: Oracle Enterprise Linux 6.7
	Client: MS Windows 7/10	Client: MS Windows 7, Windows 10
	Mobile Client and Server: MS Windows 7/10	Mobile: Apple iOS 11, Android 7
	Fixed Branch Client: MS Windows Embedded Standard 7	Information not available on the 510(k) Summary available on the FDA website.
	Reference Lab Server: Oracle Enterprise Linux version 6.4	
	Reference Lab Admin. Server: Oracle Enterprise Linux version 6.4	Information not available on the 510(k) Summary available on the FDA website.
	Reference Lab and Reference Lab Admin Client: MS Windows 7/10	
Client Hardware Requirement	CPU Intel Pentium 4 2.80 GHz, 1 GB RAM Electronic signature pad: Symbol LS4278, Topaz T-L755-HSB or Elo 1515L - LCD Touch Screen Display E210772 Barcode Scanner: Symbol LS2208, LS1902, LS4278 or Zebra DS 4608 Scale: Ohaus Scout Pro SP2001	Information not available on the 510(k) Summary available on the FDA website.

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	Subject Device RSA 2.0	Predicate BBIMS Version 2.06.00 BK180246
Mobile Hardware Requirement	Server: CPU Intel Core(TM) i5-8365U @ 1.60 GHz 8 GB RAM, Zebra DS4608 Client: CPU Intel Core(TM) i5-8365U @ 1.60 GHz 8 GB RAM, Zebra DS4608	Apple or Android phone utilizing iOS 11 or Android 7
Tablet Requirements	Dual Core @ 1GHz 16 GB Internal Memory, Up to 32GB Expandable 8.0 Megapixel Wi-Fi 802.11a/b/g/n/ac Android 8.1.0 Oreo	Information not available on the 510(k) Summary available on the FDA website.
Server Hardware Requirement	CPU Intel(R) Xeon(R) CPU E5-2660 v3 @ 2.60GHz (4 CPUs Allocated) 32 GB RAM	Information not available on the 510(k) Summary available on the FDA website.

Technological Characteristics:

As described in the table above, both applications are based on an Oracle database. While programming development technologies are different, both utilize similar Oracle-based languages. Internet explorer is used for system access. Mobile hardware is different but does not affect system functionality.

Substantial Equivalence:

The proposed RSA application is substantially equivalent to the legally marketed BBIMS application in intended use, features and technological characteristics.

Both systems provide management controls and information services that have been designed to assist personnel in the operation of a blood center. These controls include:

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Non-Clinical Testing:

Based upon non-clinical testing, the RSA Version 2.0 device was found to be safe for its intended use and is substantially equivalent to the predicate device in terms of intended use, functionality, technological characteristics as well as safety and effectiveness.