SECTION 5: 510(K) SUMMARY

Establishment Registration Number: 3028885

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Submission prepared on November 11, 2022

Device:

Proprietary Name:	Blood Bank Control System, Version 6.0
Common Name:	Blood Establishment Computer Software
Classification:	Class II, product code 81MMH
Panel:	Hematology

Predicate: ABO Express, Version 2.0.0 (BK040056)
ABO Wheels, Version 1.0.0 (BK140184)
ABO QuickPass, Version 1.0.0 (BK140198)

Device Description:
Blood Bank Control System, V6.0 is a software only device manufactured by Blood Bank Computer Systems, Inc. (BBCS) that is a comprehensive software device that aids in the management of donor and transfusion services. The donor screening and blood collection services are used to establish the eligibility of the donor to donate a given procedure, and ensure that the donor screen and phlebotomy information is complete. The product manufacturing and testing services are used to determine the component was created in accordance with the acceptable time thresholds as well as determine information that would be used for ISBT labeling. Additionally, the device will determine which tests are required for release of the blood product and can be used to evaluate the completeness of the testing for release. The patient transfusion services can determine the suitability for crossmatch.

Intended Use:
Blood Bank Control System V6.0 is intended to be used by trained personnel to aid in the collection, manufacture and distribution of blood and blood components. The software is designed to identify eligible donors by the use of both user or donor administered history questionnaire functionality (Computer Assisted Self Interviews (CASI)) along with additional system logic to determine donor eligibility which includes testing as well as donor health screening. The system prevents the release of unsuitable blood and blood components for transfusion or further manufacturing by performing compatibility testing and aids in the manufacture, labeling and shipment of blood and blood products. The system supports the determination of compatibility status of product per patient for transfusion service operations.

Device Comparison Table:

Areas of Comparison	Blood Bank Control System, Version 6.0	Predicate - ABO Express	Predicate – ABO Wheels	Predicate – ABO QuickPass

Hardware	Cloud Supplied Hardware or x64 PC/Server	IBM iSeries (AS/400)	PC	PC/Server
Operating Systems	Cloud Supplied OS or UBUNTU Linux Server	IBM iSeries OS V6R1, V7R1, V7R3	Windows10 and Server 2008 and 2012	Windows Server 2012
Web Server				Apache HTTP Web Server 8.0
Programming Language	Java Open JDK 14	IBM RPG IV	Java 1.7	Java 1.6
Database	None	IBM DB2	MySQL 5.7	None
Communication Protocols	TCP/IP	TCP/IP	TCP/IP	TCP/IP

Technological Characteristics:
As described in the table above, the proposed and predicate devices have similar technology in hardware, software, and peripheral usage, with the primary technological difference being Blood Bank Control System V6.0 is now accessed through application programming interfaces (APIs). While there are minor differences in principles of operation and technology characteristics between the proposed Blood Bank Control System V6.0 software device and the predicate devices, no new questions of safety or effectiveness were raised.

The proposed Blood Bank Control System V6.0 software is substantially equivalent to the Predicate devices listed in terms of intended use, performance, technology characteristics, safety and effectiveness.

Performance Data:
The following performance data is provided in support of the substantial equivalence determination.

Non-Clinical Testing
Blood Bank Computer Systems' activities to assure adherence to design control include determining new risks introduced by the new functionality and analyzing those risks. Hazards are mitigated by identifying new requirements to reduce the hazard, providing appropriate warnings to the user or adding warning statements to the product labeling.

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 by the requirements. The hazards, requirements and associated test cases are used to create the Traceability Analysis Matrix.

Alpha validation was comprised of Component Verification (CV) Testing and System Level Testing (SLT). CV Testing was performed to ensure the system had met its intended use and implementation of all new requirements was successful and can be viewed in the Traceability Matrix. Any subsequent changes are assessed for necessary regression testing. The results of alpha validation demonstrated that safety critical functionality performed as expected. All failures were evaluated by a subject matter expert (SME) and either corrected or scheduled for future correction based upon risk.

Beta validation was conducted at two user facilities, using the System Level Tests provided by BBCS (along with client specific configurations). The results of beta testing demonstrated that the software functioned as expected and met the required specifications.

Clinical Testing:
Clinical performance testing is not applicable for Blood Bank Control System, V6.0 as it is a software only device.

Conclusions:
Blood Bank Control System V6.0 was developed using the design controls incorporated in Blood Bank Computer Systems development processes, which are based on the quality system regulations. The *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices dated May 11, 2005* and the *Guidance for Format for Traditional and Abbreviated 510(k)s dated September 13, 2019* were also both used.

The non-clinical data supports the safety of the device and indicate that the software device will perform as well as the predicate device as demonstrated by the alpha and beta testing. The testing assessment verifies that the device performs as designed, per the functional requirements, when utilized within its intended use.