510(k) SUMMARY (BK200491)

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Device:
Trade Name: *i*WeBB *electronic* Laboratory Information System (*i*WeBB-*e*LIS) v1.0.0
Classification Name: Blood Establishment Computer Software and Accessories
Device Class: Class II
Product Code: MMH
Panel: Hematology
Regulation Number: 21 CFR § 864.9165

Device Description:
*i*WeBB *electronic* Laboratory Information System (*i*WeBB-*e*LIS) v1.0.0 is Blood Establishment Computer Software intended to manage the transfusion process including patient records, order requests, laboratory testing results, blood product fulfillments, and transfusion histories.

Indication for Use:
*i*WeBB *electronic* Laboratory Information System (*i*WeBB-*e*LIS) v1.0.0, also referred to as *e*LIS, is software intended for use by trained blood banking laboratory personnel for managing patient information, blood transfusion requirements, blood specimen test orders, laboratory test results, blood product orders (including safety/compatibility checks for attributes, antibodies, and antigens), and patient transfusion histories. *e*LIS also interfaces to popular blood testing laboratory equipment and provides system reporting, printing, and data exporting features.

Predicate Device:
Trade Name: SafeTrace Tx 4.0.0
510(k) Number: BK180209
510(k) Holder: Haemonetics Corporation, 125 Summer St., Boston, MA 02184

No reference devices were used in this submission.

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Comparison of Technological Characteristics with the Predicate Device:

Parameter/Character	Subject Device *i*WeBB-*e*LIS v1.0.0	Predicate Device SafeTrace Tx® 4.0.0
Intended Use	Electronic information system used by a single-site to manage the blood transfusion process. It manages and tracks blood product information from procurement to final disposition.	Electronic information system used by single-site, multi-site and centralized transfusion services to manage the blood transfusion process. It manages and tracks blood product information from receipt to final shipment and disposition.
Indication For Use	Same as predicate device	Electronic information system that manages the blood transfusion process and assists in the determination of the suitability of released products.
	It manages and tracks blood product information relating to procurement, testing, issuing, and final disposition.	It manages and tracks blood product information relating to receipt, reservation, modification, testing, and final shipment and disposition.
	Same as predicate device	The application manages and provides a centralized view of patient, visit, and order information, including positive patient identification and patient, testing and transfusion history.
	Same as predicate device	The system can perform electronic crossmatching and safety and compatibility checks between patient and product.
	Same as predicate device	Component attributes, such as human leukocyte antigen (HLA) attributes, can be entered.
	Same as predicate device except no interface to hospital information systems or blood tracking and/or storage devices.	Can operate stand-alone or interface with: • Labeling systems • Test lab systems, analyzers, and equipment • Hospital information systems • Laboratory information systems • Blood tracking and/or storage devices • Inventory systems (including other Blood Establishment Computer Software (BECS)
Target Population	Same as predicate device	Trained blood banking laboratory personnel performing transfusion management activities
Technology	Same as predicate device	• Brower-based transfusion management system with an interactive dashboard • Standard security features and auditing tools • Reporting capability
Materials	Same as predicate device	N/A
Energy Source	Same as predicate device	Powered by a computer operating system
Performance	Same as predicate device	Equal to the needs required of its users

Parameter/Character	Subject Device *i*WeBB-*e*LIS v1.0.0	Predicate Device SafeTrace Tx® 4.0.0
Technological Characteristics – Design	The technological characteristics are identical or similar to those of the predicate device. No new safety or effectiveness issues are introduced.	Transfusion management system that supports the following: • Access comprehensive patient information • Automatically perform extensive safety and compatibility checks between patient and product • Track, manage and assign work • Safely and quickly release emergency blood products • Maintain transfusion safety • Communicate with testing instruments and analyzers • Maintain one consolidated patient history record • Manage orders, specimens and blood products from multiple facilities in a single database • Perform remote, electronic and routine crossmatches
Database Server	• Microsoft® Windows Server® 2019 (licensed) • SQL Server Database 2017 • Intel Xeon CPUs	• Windows based • Oracle relational database • Intel based
Application Server	• Microsoft® Windows Server® 2019 (licensed) • Microsoft Internet Information Services (IIS) 10.0 • Microsoft .NET Framework 4.5; Microsoft Visual C#® and C++® Redistributable for Visual Studio® 2012 Update 4; Oracle® 12c Client Runtimes for Microsoft Windows® (x64) • eLIS Windows Service v1.0 for ECHO • Intel Xeon CPUs	• Windows based • Oracle software • Intel based
Devices	• IMMUCOR ECHO v2.1.0.41 • Luminex System X200 • LifeTrak 2013	• Interfaces with laboratory devices • Interfaces with blood bank information systems
Hardware Platform (Personal Computers)	• Windows7 64bit SP1 | Adobe® Reader XI, IE 11, Chrome Version 80.0.3987.163 (64-bit) | CPU: 2.8 GH+* z • Printers • Scan Guns	• Windows based • Industry standard

Comparison Summary
*i*WeBB *electronic* Laboratory Information System (*i*WeBB-*e*LIS) v1.0.0 manufactured by Carter BloodCare is substantially equivalent to SafeTrace Tx® 4.0.0 manufactured by Haemonetics Corporation, that was cleared by FDA on August 7, 2018. *e*LIS and the predicate are both Blood Establishment Computer Software intended for use by trained blood banking laboratory personnel for managing the transfusion process. *e*LIS has the identical or similar technological characteristics in regard to design, function and application as the corresponding parts of the referenced predicated device. Both are software products and do not have different materials, energy source, or performance characteristics.

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

Sterilization and Shelf Life Testing: Not Applicable (Standalone Software)

Biocompatibility Testing: Not Applicable (Standalone Software)

Software Verification and Validation Testing
Software verification and validation activities included unit, structural, module, system, functional, and integrated testing. Testing ensured that all functional requirements, algorithms, processes, and business rules included within the system operated accurately as a whole and met risk control measures and performance criteria.

Electrical Safety and Electromagnetic Compatibility (EMC): Not Applicable (Standalone Software)

Mechanical and Acoustic Testing: Not Applicable (Standalone Software)

Performance Testing – Bench
User acceptance/performance testing was performed by subject matter experts (SMEs) familiar with Reference and Transfusion processes, certified medical technologists (MLTs/MTs), and experienced specialists in blood banking technology (SBB) and verified the system met expectations and specified requirements for its intended use.

Performance Testing – Animal
Animal testing was not required to demonstrate safety and effectiveness of the device

Performance Testing – Clinical
Clinical testing was not required to demonstrate safety and effectiveness of the device

Conclusion:
The overall performance data in this submission supports that *i*WeBB-*e*LIS v1.0.0 is safe, effective, and substantially equivalent to the predicate device when utilized for its intended use. 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.