Section 5

510(k) Summary

(in accordance with 21 CFR 807.92)

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Submitter:
Haemonetics Corporation
400 Wood Rd.
Braintree, MA 02184

Contact:
Kimberley Gleeson
Senior Regulatory Affairs Specialist
Phone: 1-916-586-9717
Fax: 1- 781-356-3558
Email: kimberley.gleeson@haemonetics.com

Proposed Device Information:

Trade Name:	SafeTrace Tx 4.0.0 (Haemonetics Corporation)
Common Name:	Blood Establishment Computer Software (BECS) and Accessories
Product Code:	MMH
Device:	Stand-alone Blood Bank Software
Review Panel:	Hematology
Device Class:	Class II

Predicate Device Information:

1.

Trade Name:	SafeTrace Tx 3.12.0
Common Name:	Blood Establishment Computer Software (BECS)
510(k) Number:	BK150360
Product Code:	MMH
Device:	Stand-alone Blood Bank Software
Review Panel:	Hematology
Device Class:	Unclassified

2.

Trade Name:	HCLL™ Transfusion, Version 2012
Common Name:	Software, Blood Bank, Stand Alone
510(k) Number:	BK120036
Product Code:	MMH
Device:	Stand-alone Blood Bank Software
Review Panel:	Hematology

Device Class: Unclassified

Device Description

The proposed SafeTrace Tx 4.0.0 is an electronic information system intended to manage the transfusion process, including maintaining a complete test and transfusion history for a patient. The software application supports tracking of items needed to manage the transfusion process from receipt to final disposition.

Intended Use:

SafeTrace Tx is an 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.

Indications for Use:

SafeTrace Tx is an 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 receipt, reservation, modification, testing, and final shipment and disposition. The application manages and provides a centralized view of patient, visit, and order information, including positive patient identification and patient testing and transfusion history.

The system can perform electronic crossmatching and safety and compatibility checks between patient and product. Component attributes, such as human leukocyte antigen (HLA) attributes, can be entered into SafeTrace Tx.

SafeTrace Tx 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) systems)

Substantial Equivalence:

The software device, SafeTrace Tx 4.0.0, is substantially equivalent to the software devices Haemonetics SafeTrace Tx 3.12.0 (Predicate 1) and Mediware HCLL Transfusion, Version 2012 (Predicate 2).

SafeTrace Tx 4.0.0 uses similar technology as its predicate devices. While there are minor differences in technological characteristics and principles of operation between the proposed device and its predicate devices, none of these differences raise new types of safety or effectiveness questions. This demonstrates that the technology used in the SafeTrace Tx 4.0.0 software device is substantially equivalent to the technology used in one or more of the predicate devices.

The SafeTrace Tx 4.0.0 software device and its predicates are equivalent to or the same with respect to mapped intended use, functionality, performance, and technological characteristics, as well as safety and effectiveness.

Clinical Trials

Clinical performance testing is not applicable for SafeTrace Tx 4.0.0, as it is a software only product.

Conclusion

SafeTrace Tx 4.0.0, was developed in accordance with 820.30 Design Controls as well as the *"FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)."* The software was thoroughly tested including verification, validation, and user acceptance (Beta) testing to ensure it is as safe, as effective, and performed as well as each predicate device`s functionality, when utilized within its intended use and in accordance with labeling, as demonstrated by the testing performed.

Based on the functionality and performance comparison, technological characteristics comparison and the intended use, the SafeTrace Tx 4.0.0 stand-alone software device performs as intended in all aspects of the predicate devices' mapped functionality characteristics. The safety aspects of the SafeTrace Tx 4.0.0 stand-alone software device have been thoroughly tested in accordance with validation practices as outlined in 820.30, Design Controls. The SafeTrace Tx 4.0.0 stand-alone software device is substantially equivalent to the predicate devices in terms of intended use, functionality, performance, technological characteristics as well as safety and effectiveness.