Section 5

510(k) Summary

(in accordance with 21 CFR 807.92)

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Proposed Device Information:

Trade Name:	InstaMatch 1.0.0 (Haemonetics Corporation)
Common Name:	Software, blood bank, stand alone products
Product Code:	MMH
Device:	Stand-alone Blood Bank Software
Review Panel:	Hematology
Device Class:	Unclassified

Predicate Device Information:

1. Trade Name: SafeTrace Tx 3.12.0 (Haemonetics Corporation)

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. Proprietary Name: LifeTrak® Version 2012 (Mediware Information Systems Inc.)

Common Name:	Software, Blood Bank, Stand Alone
510(k) Number:	BK120039

Classification Name: Unclassified

Device Description

The proposed InstaMatch 1.0.0 is a configurable and interactive web-based computer software application that provides searching and matching capabilities for patients, donors and blood products in inventory that possess specific attributes or characteristics, such as human leukocyte antigen and antibodies (HLA), ABO/Rh, and cytomegalovirus (CMV) status. The application has been designed to help medical professionals determine the degree of HLA match between patient and blood products and between patients and blood donors.

Intended Use:

InstaMatch is a configurable, web-based software tool that queries a Blood Establishment Computer Software (BECS) for blood products and donors compatible with patients requiring specific needs, such as human leukocyte antigens (HLA). The tool calculates a grade and site-configurable score indicative of HLA compatibility between donor, product and patient.

Indications for Use:

InstaMatch is a configurable, web-based software tool used by medical professionals at Donor Centers and/or Hospital/Transfusion facilities. InstaMatch provides searching and matching capabilities for patients, donors and blood products that possess specific attributes or characteristics, such as human leukocyte antigens (HLA), ABO/Rh, CMV status, and antibodies. InstaMatch provides the following functionalities:

- Interfaces with Blood Establishment Computer Software (BECS).
- Finds compatible blood products and donors in the BECS database based on attributes such as HLA information.
- Provides donor and/or product details after a search is performed.
- Calculates a grade and site-configurable score indicative of HLA compatibility between donor, product and patient.

Substantial Equivalence

The proposed software device, InstaMatch 1.0.0, is substantially equivalent to the software devices Haemonetics SafeTrace Tx 3.12.0 (Predicate 1) and Mediware LifeTrak® Version 2012 (Predicate 2).

The proposed InstaMatch 1.0.0 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 proposed InstaMatch 1.0.0 software device is substantially equivalent to the technology used in one or more of the predicate devices.

The proposed InstaMatch 1.0.0 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 InstaMatch 1.0.0, as it is a software only product.

Conclusion

The proposed device, InstaMatch 1.0.0, 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 proposed InstaMatch 1.0.0 device performs as intended in all aspects of the predicate devices' mapped functionality characteristics. The safety aspects of the proposed InstaMatch 1.0.0 device have been thoroughly tested in accordance with validation practices as outlined in 820.30, Design Controls. The proposed InstaMatch 1.0.0 software device is substantially equivalent to the predicate devices in terms of intended use, functionality, performance, technological characteristics as well as safety and effectiveness.