Section 5

510(k) Summary

(in accordance with 21 CFR 807.92)

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Submitter:
Haemonetics Corporation
4925 Robert J Mathews Pkwy., Suite 100
El Dorado Hills, CA 95762, USA

Contact:
Allyson Parks
Regulatory Specialist
Phone: 1-916-404-8506
Fax: 1-916-357-7167
Email: allyson.parks@haemonetics.com

Proposed Device Information:

Trade Name:	NextGen 3.0.0 (Haemonetics Corporation)
Common Name:	Blood Establishment Computer Software (BECS)
Product Code:	MMH
Device:	Stand-alone Blood Bank Software
Review Panel:	Hematology
Device Class:	Unclassified

Predicate Device Information:

1.

Trade Name:	NextGen 2.0.0 (Haemonetics Software Solutions)
Common Name:	Blood Establishment Computer Software (BECS)
510(k) Number:	BK130082
Product Code:	MMH
Device:	Stand-alone Blood Bank Software
Review Panel:	Hematology
Device Class:	Unclassified

2.

Trade Name:	Fenwal DXT Relay, Software Version 2.0
510(k) Number:	BK110025
Product Code:	MMH
Device Class:	Unclassified

Device Description

The proposed NextGen 3.0.0 is a computer software system that is intended to assist in the management of donors and blood products. The product is a configurable and interactive application that automates the processes of a donation center. The system manages the donor visits, records the donations, tracks test samples and results, and manages the shipment of units out of the center. The device includes many safety checks to ensure donor suitability and unit releaseability requirements are met.

Intended Use

NextGen is a configurable and interactive electronic information management system used in plasma donation centers. The device assists in the management of data related to donors, their suitability to donate, collection of blood products, product testing, labeling, storage, manufacturing, and shipping. NextGen also assists in managing data related to equipment, supplies, and quality assurance needed for the business operation of a donation center.

Indications for Use

NextGen is designed to undertake donation center operations including but not limited to recruitment of donors, screening of donors for suitability, immunizations, blood product collection processing, crossmatching, and providing lookback capabilities. NextGen manages donor information and allows multiple methods to identify donors, including biometrics such as fingerprints. NextGen is also designed to manage donor and product testing, labeling, barcode scanning, equipment, supplies, quality assurance, inventory, shipping, and product release. The NextGen questionnaire and phlebotomy functionalities can operate stand-alone. NextGen can interface with:

- External donor management systems
- Cross donation check systems
- Apheresis devices
- Screening test instruments
- Test lab systems
- Deferral registry systems
- Other BECS systems

Substantial Equivalence

The proposed software device, NextGen 3.0.0, is substantially equivalent to the software devices Haemonetics NextGen 2.0.0 (Predicate 1) and Fenwal DXT Relay 2.0 (Predicate 2).

The proposed NextGen 3.0.0 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 NextGen 3.0.0 software device is substantially equivalent to the technology used in one or more of the predicate devices.

The proposed NextGen 3.0.0 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 NextGen 3.0.0, as it is a software only product.

Conclusion

The proposed device, NextGen 3.0.0, 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 NextGen 3.0.0 device performs as intended in all aspects of the predicate devices mapped functionality characteristics. The safety aspects of the proposed NextGen 3.0.0 device have been thoroughly tested in accordance with validation practices as outlined in 820.30, Design Controls. The proposed NextGen 3.0.0 software device is substantially equivalent to the predicate devices in terms of intended use, functionality, performance, technological characteristics as well as safety and effectiveness.