

# Section 5

## 510(k) Summary

(in accordance with 21 CFR 807.92)

**Date:** March 3, 2016

**Submitter:**

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**Proposed Device Information:**

Trade Name:	EIDorado Donor 4 Next Generation Donor Management Solution 1.0.0 (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: | EIDorado Donor 3.0.0                         |
| Common Name:   | Blood Establishment Computer Software (BECS) |
| 510(k) Number: | BK150308                                     |
| Product Code:  | MMH  |
| Device:        | Stand-alone Blood Bank Software              |
| Review Panel:  | Hematology                                   |
| Device Class:  | Unclassified                                 |
| 2. Trade Name: | NextGen 2.0.0                                |
| Common Name:   | Blood Establishment Computer Software (BECS) |
| 510(k) Number: | BK130082                                     |
| Product Code:  | MMH  |

Device:	Software, Blood Bank, Stand Alone Products
Review Panel:	Hematology
Device Class:	Unclassified

## **Device Description**

The proposed EIDorado Donor 4 Next Generation Donor Management Solution 1.0.0 software is a Blood Establishment Computer System (BECS) that is intended for use in blood collection and manufacturing facilities to manage donors, blood, blood products and to maintain electronic records for end-to-end traceability and auditing. The application supports the complete blood management process from collection, manufacturing, testing and labeling to distribution.

The proposed EIDorado Donor 4 Next Generation Donor Management Solution 1.0.0 software is accessible using a commercial off-the-shelf web browser on a computing device (e.g. laptop or desktop) at the donation centers or in a mobile donation environment.

The proposed EIDorado Donor 4 Next Generation Donor Management Solution software does not directly incorporate any wireless technology. The wireless technologies used with the software are integrated into the commercial off-the-shelf computing hardware devices from which EIDorado Donor 4 Next Generation Donor Management Solution is accessed.

## **Intended Use:**

EIDorado Donor 4 Next Generation Donor Management Solution is an electronic information management system intended for use in facilities and mobile environments that manage donors and blood products. It supports the complete blood management process from collection, manufacturing, testing and labeling to distribution.

## **Indications for Use:**

EIDorado Donor 4 Next Generation Donor Management Solution is intended for use in facilities and mobile environments to provide full traceability of blood components along with safety checks to prevent ineligible donors from donating and to prevent the release of unsafe blood components. The software can perform self/staff-assisted questionnaires and record donor questionnaire assessment results. EIDorado Donor 4 Next Generation Donor Management Solution can operate stand-alone or interface with:

- Donor Management Systems
- Labeling systems
- Test Lab systems
- Apheresis devices and collection equipment

## **Substantial Equivalence**

The proposed software device, EIDorado Donor 4 Next Generation Donor Management Solution 1.0.0, is substantially equivalent to the software devices Haemonetics EIDorado Donor 3.0.0 (Predicate 1) and Haemonetics NextGen 2.0.0 (Predicate 2).

The proposed EIDorado Donor 4 Next Generation Donor Management Solution 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 EIDorado Donor 4 Next Generation Donor Management Solution 1.0.0 software device is substantially equivalent to the technology used in one or more of the predicate devices.

The proposed EIDorado Donor 4 Next Generation Donor Management Solution 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 EIDorado Donor 4 Next Generation Donor Management Solution 1.0.0, as it is a software only product.

## **Conclusion**

The proposed device, EIDorado Donor 4 Next Generation Donor Management Solution 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 EIDorado Donor 4 Next Generation Donor Management Solution 1.0.0 device performs as intended in all aspects of the predicate devices’ mapped functionality characteristics. The safety aspects of the proposed EIDorado Donor 4 Next Generation Donor Management Solution 1.0.0 device have been thoroughly tested in accordance with validation practices as outlined in 820.30, Design Controls. The proposed EIDorado Donor 4 Next Generation Donor

Management Solution 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.