HAEMONETICS®

510(k) Summary

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Device Information

TRADE Name:	BloodTrack® Software
Common Name:	Blood Establishment Computer Software
Classification Name:	Blood Establishment Computer Software and Accessories
Regulation Number:	21 CFR 864.9165
Review Panel:	Hematology
Product Code:	MMH
Device Class:	2

Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
BK140133	BloodTrack 4.7.0	MMH

Device Description Summary
The BloodTrack® 4.16.0 is software designed to be used in a healthcare or collection facility to manage the inventory of blood, blood products and plasma derivatives (collectively referred to as Units), to manage the transfusion administration process at the patient bedside and to maintain electronic records for end-to-end traceability and auditing.

Intended Use
The BloodTrack software is an electronic information management system intended to monitor the reception, handling, transportation and transfusion of blood and blood products.

The BloodTrack software assists in the selection of blood products for patients by providing positive patient identification for transfusion, and verifying that the identified blood product was obtained.

Indications for Use
The BloodTrack software is indicated for use to assist in positive patient identification for transfusion, to assist in the selection of blood products for patients and verify that the identified blood product was obtained.

Indications for Use Comparison

The Indications for Use for the BloodTrack® Software 4.16.0 are different from the predicate device, BloodTrack 4.7.0, because the indications for use were clarified to describe only the medical functionality and to remove non-medical functionality, which were not critical to the safety and effectiveness of the software device when used as labeled. The currently cleared indications of the predicate (BK140133) continue to be supported.

Technological Comparison

There is no change to the underlying technology, or principle of operation from the predicate BloodTrack 4.7.0 (BK140133). The device functions with the same intended use to monitor the reception, handling, transportation and transfusion of blood, blood products and plasma derivatives (collectively referred to as Units). Through the discussion on substantial equivalence, the risk management documentation, and the testing provided, it is concluded that the changes associated with BloodTrack 4.16.0 do not change the risk-benefit profile of the BloodTrack® Software.

Non-Clinical and/or Clinical Tests

The non-clinical testing performed to support this premarket submission was performed in accordance with the FDA Guidance, *General Principles of Software Validation (2002)*. The software testing consisted of thorough verification and validation testing to ensure the subject device is as safe, as effective, and performed as well as or better than the predicate device.

No clinical testing was performed in support of this premarket submission for the BloodTrack® Software.

Summary & Conclusions

The non-clinical testing and comparison to the predicate device show the subject BloodTrack® Software 4.16.0 to be substantially equivalent to the predicate device and that there is no impact to the safety and effectiveness of the device.

Results from the non-clinical testing demonstrate that the BloodTrack® Software 4.16.0 is as safe and effective, and it performs as well as its proposed predicate device.

In conclusion, the BloodTrack® Software 4.16.0 is substantially equivalent to the predicate device in terms of functionality, performance, technological characteristics, and Indications for Use, including for safety and effectiveness.