Section 5
510(k) Summary

(in accordance with 21 CFR 807.92)

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Proposed Device Information:
Trade Name: BloodRelay 1.0.0
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:
Trade Name: LifeTrak® Version 2012
Common Name: Software, Blood Bank, Stand Alone
510(k) Number: BK120039
Product Code: MMH
Device: Stand-alone Blood Bank Software
Review Panel: Hematology
Device Class: Unclassified

Device Description:
BloodRelay is a software-only device. Blood product inventory transactions may be managed in the software. Records of blood unit processing and movement to other locations may be tracked. Inventory and all associated transactions may be searched for.

Intended Use:
BloodRelay is a blood bank application that may be used stand-alone. The system is designed to assist authorized and trained personnel who are actively engaged in the management of blood product inventory. Site-validated third-party systems may integrate with the system to support functions such as blood product inventory management.

The system supports operations for blood suppliers such as inventory management and distribution of blood products, tracking product disposition and searching for blood products.

Indications for Use:
BloodRelay is intended to integrate with site-validated third-party systems and assist authorized and trained blood bank personnel to:

Record and manage ISBT 128 blood product inventory associated information such as donation identification number (DIN), product code, expiration date/time and blood type.

Record and manage blood product inventory dispositions such as shipment and quarantine.

Search and locate specific blood products to facilitate tasks such as quarantining inventory to remove unsuitable units.

Substantial Equivalence:
The proposed BloodRelay v.1.0.0 software device is substantially equivalent to LifeTrak® Version 2012's Distribution module (Predicate). It has a similar intended use and technological features and capabilities. While there are minor differences in principles of operation and technology characteristics between the proposed BloodRelay v1.0.0 software device and the Predicate, no new questions of safety or effectiveness were raised.

The proposed BloodRelay v.1.0.0 software device is substantially equivalent to the Predicate device listed in terms of intended use, functionality mapped, performance, technology characteristics, safety and effectiveness.

Clinical Trials:
Clinical performance testing is not applicable for BloodRelay 1.0.0 as it is a software only device.

Conclusion:
The proposed BloodRelay 1.0.0 software device was developed using an established design control process for software development based on 21 CFR part 820.30 Design Controls. The *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices dated May, 2005* was also used. The proposed device was extensively tested at the verification and validation levels, including testing to ensure the proposed device meets its intended use including safety critical requirements. Beta testing was also completed at a user site to ensure user acceptance. The results of beta testing demonstrated that the proposed BloodRelay 1.0.0 software device meets required specifications and functions as expected with satisfactory performance times.

Based on the comparisons completed for mapped functionality, technology characteristics and intended use statements, the proposed BloodRelay 1.0.0 software device performs as intended. Safety features of the proposed BloodRelay 1.0.0 software device were tested according to practices specified in 21 CFR part 820.30 Design Controls, and all testing passed. The proposed BloodRelay 1.0.0 software device is substantially equivalent to the Predicate device listed in terms of intended use, functionality mapped, performance, technology characteristics, safety and effectiveness.