6 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary is provided.

510(k) Summary

I. SUBMITTER

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II. DEVICE

Trade Name of Device:	Vista® Information System
Common or Usual Name:	Software, Blood Bank, Stand Alone Products
Classification Name:	Blood Establishment Computer Software and Accessories
Regulatory Class:	21 CFR 864.9165
Product Code:	MMH
Classification Panel:	Hematology

III. PREDICATE DEVICE

Vista Information System, Version 4.0 (BK150228)

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

A. Device Identification

Vista Information System, Version Navigator (Navigator) is a software product; it consists of installation media and supporting documentation with the ultimate configuration determined by the customer-selected hardware platform, parameters of which are outlined in the device labeling.

NOTE: This release of Vista Information System is termed Version Navigator and will be referred to as "Navigator" throughout this document. Navigator is the next release (name/number) of the Vista Information System software.

B. Device Characteristics

Navigator is a client-server application installed on personal computers running Microsoft® Windows® operating systems.

C. Environment of Use

Navigator is intended for use in environments associated with blood component collection and manufacture.

D. Device Description

Navigator is a Microsoft Windows-based application that assists the blood center with the operations management by helping optimize productivity, collection practices, donor utilization and product management. The Vista Information System captures, stores, and evaluates procedural data from each Trima Accel system collection. Blood Center staff interacts with the Vista Information System through the Vista client, a graphical user interface (GUI) installed on desktop or laptop computers as well as barcode scanners used with the Trima Accel collection system (a Terumo BCT apheresis system cleared for blood component collections via BK170157).

Navigator is focused on increasing automation when working in conjunction with Trima Accel system(s). It is also capable of supporting donations performed on other collection devices, as well as whole blood donations, via manual data entry (known as "User Defined Machines" or UDM).

Customers may have several Trima Accel systems connected to Navigator and may also have fixed-site donation locations that are connected via a network. Note that not all capabilities must be used, as each customer determines how to install, configure, and use Navigator within defined parameters in order to best meet their needs.

E. Materials of Use

The Vista Information System (Vista System) is a software solution; it does not explicitly include materials or hardware as part of the distributed product.

F. Key Performance Specifications/Characteristics of the Device

The Vista System is a software solution. Performance characteristics are influenced by feature utilization, operator ability and implementation configuration. Detailed configuration and performance characteristics are available in the device labeling.

V. INTENDED USE

The Vista System is intended for use in automating processes in facilities that are managing blood collection, including collecting donor information and collecting blood components.

VI. INDICATIONS FOR USE

The Vista System is intended for use in facilities that are automating the process associated with managing donor information, including information about blood collection and manufacture of blood components, with the following functions:

- Managing donor data such as blood loss history, donor vital signs relevant to blood collection, and demographics
- Storing and reporting device-connected and manually entered collection procedure information
- Determining donor eligibility by considering donor blood loss history, user-configured eligibility parameters, and immediate safety qualifications
- Interfacing with the Trima® Accel Automated Blood Collection System
- Aiding in the management of these blood establishment processes:
  - Trima Accel system configuration management
  - Periodic review of platelet count and other indicators of donor health
  - Prioritization and management of blood component collection
- Exchanging data with blood establishment computer systems (BECS)
- Collecting and managing data associated with whole blood and apheresis collection procedures

VII. TECHNOLOGICAL COMPARISON

Navigator software modifications include enterprise architecture enhancements and server hardware virtualization support providing the customer increased deployment flexibility. Associated technology updates allow upgrades to the environment in which the system runs to address obsolescence issues.

These software modifications will update the functionality of the interface with Navigator to include a complete procedural interaction. A complete procedural interaction ensures a complete procedure record is obtained through real-time data collection, capability of a playback functionality and receipt of the procedure data log (dlog) processing through the Vista playback service.

Navigator is focused on modifications and technical upgrades to be compatible with Trima Accel's Version 7.

Modifications include:

- Updating to NET 4.5.2
- Vista Client: Add Support for Windows 10 and Remove Windows 2008 R2 Terminal Server
- Database: Update to Oracle 12c Release 2
- Database on Linux: Add OPENSUSE, Remove Red Hat
- Browser: Remove Microsoft Internet Explorer (IE) 10, add Microsoft Edge (v40.15063.674.0) and Google Chrome (v60.0.3112.118)
- Interface with Software Cadence
  - Remove retrieval of Dlogs from DMS
  - Manage Dlog retrieval through interface with Software Cadence

See Section 3 for a complete and detailed description of software modifications for Navigator. Known Anomalies and work arounds are also listed and presented in Section 3.

Navigator incorporates the same essential technological characteristics, device design, and operating principal as the predicate for each core design feature. Therefore, Navigator is at least equivalent to a legally marketed predicate with respect to essential technology and technological characteristics.

VIII. PERFORMANCE DATA

The following non-clinical performance data were provided in support of the substantial equivalence determination.

A. Mechanical Testing

Mechanical testing is not applicable to Navigator as it is a software only product.

B. Biocompatibility Testing

Biocompatibility testing is not applicable to Navigator as it is a software only product.

C. Electrical Safety and Electromagnetic Compatibility (EMC) Testing

Electrical safety and EMC testing is not applicable to Navigator as it is a software only product.

D. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by IEC 62304:2006 Medical Device Software – Software life cycle processes. The software level of concern is considered "major".

E. Sterility Testing

Sterility testing is not applicable to Navigator as it is a software only product.

F. Stability/Shelf Life Testing

Stability testing is not applicable to Navigator as it is a software only product.

G. Clinical Studies

Clinical testing is not applicable to Navigator as it is a software only product.

IX. CONCLUSIONS

The proposed device, Navigator, was developed in accordance with *IEC 62304:2006 Medical Device Software – Software life cycle processes*. The verification and validation data provided in this notification demonstrate that Navigator is substantially equivalent with regard to the safety and efficacy of the previously cleared Vista Information System, Version 4.0.

Navigator incorporates the same essential technological characteristics, device design, and operating principal as the predicate for each core design feature. Therefore, Vista Information System, Version Navigator is at least equivalent to a legally marketed predicate with respect to intended use, essential technology, and bench performance.