

GAMBRO Vista Information System
Summary of Safety and Effectiveness

GAMBRO Vista Information System

Manufacturer: GAMBRO BCT, Incorporated
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Trade Name of Device: The GAMBRO BCT Vista Information System, Independent Solution

Common Name: Blood Bank Information Management System.

Classification Name: The product code is 81MMH

Predicate Devices: Wyndgate Technologies SafeTrace TX
(510(k) BK980023)
Digi-Trax Corporation Digi-Trax Donor-ID 2.0
(510(k) BK000020)
Information Data Management System IDM Select
(510(k) BK000020)
COBE Trima System
(510(k) BK970023)
COBE ApolloNet
(510(k) Not Applicable)

Device Description

The Vista Information System (Independent Solution) is a Microsoft Windows based application that allows the blood center to improve the management of the blood center operations by increasing productivity, improving manufacturing practices, provide better donor utilization and improved product management for apheresis donors. The Vista Information System improves the record keeping of the blood center by automatically recording the run information from Trima Apheresis Systems connected with the Vista Information System. The Vista Information System also determines eligibility to donate various blood

components using donor's donation history and the donation guidelines established by the blood center. The Vista Information System allows the blood center personnel to perform various functions currently performed manually. The main features of the Vista Information System are:

- Allow the blood center to process a donor starting from check-in to completion of the procedure.
Manage donor qualification to assure the donor is eligible to donate desired products based on the center's policies, donor information and donor's donation history. The Vista Information System does not perform deferral management, blood component traceability or product inventory management functions. These functions are performed by the center's Blood Bank System.
Determine optimum procedure and blood products to be collected based on the center's needs, donor information and donor's donation history.
- Define Trima System Configuration to yield optimum blood products.
- Send Configuration data to the Trima System.
Download Donor information such as Height, Weight, Gender, Hematocrit, Platelet Precount and donor identification to the Trima System for display on the Trima System and confirmation by the operator.
Monitor Trima System status and procedure data.
Collect and apheresis procedure information including supply information from Trima systems.
Allow the operator to enter procedure data for procedures performed on other apheresis systems and Whole Blood collections.
- Allow the operator to enter product volume/quality information returned from the laboratory such as platelet count, WBC/RBC contamination levels.
Maintain a database of donor information, donation history, procedure data, laboratory data and machine configuration settings. The Vista Information System also allows the blood center to import donor information from a blood bank system into the Vista Information System database.
- Generate procedure, donor, production and configuration reports.
- Manage access to Vista Information System by operators and system administrators.

Intended Use:

The Vista Information System is a computer software package that manages the information needs of a associated with apheresis procedures. The Vista Information System is intended to be used for the following:

- Provide capability for the operator to identify current and new donors
- Collection of data from apheresis procedures performed on Gambro BCT Trima Systems.
Provide manual capability for the operator to enter procedure data for procedures performed on Gambro BCT Spectra Systems and non-Gambro BCT Systems including manual blood collections.
- Maintains a complete record of blood component donation including supplies used
Determine eligibility of donor to donate specific blood components (platelets, plasma, red blood cells)
- Set up the Trima System with Configuration and donor data

Technological Comparison:

The GAMBRO Vista Information System (Independent Solution) technological characteristics are equivalent to the technological characteristics of the Wyndgate Technologies Safe Trace TX. The technological characteristics of the Vista Information System include the hardware and underlying database system.

Non-clinical System Testing:

The Software testing and validation activities have included design reviews, hazard analysis, code audits and software testing. Software test plans were developed and used to perform software validation. Software development is based upon Spiral Development Process and uses Object Oriented Software Development Methodology. Prototype systems have been used to obtain customer preference information. Software specification, software design and software coding and validation activities have been completed. Beta testing of the Vista Information System version 2 software intended for sale has been completed.

Clinical (Beta) Testing

Two beta versions of the Vista Information System have been used in the field to obtain customer feedback and customer preference information. Additional systems have been used with focus groups to obtain customer feedback. Beta testing of version 2 software intended for sale has been completed.

Conclusion

These data demonstrate that the GAMBRO Vista Information System (Independent Solution) can help the blood center personnel improve the management and data collection operations associated with apheresis collection procedures. The Vista Information System helps in reducing errors associated with data recording and set up of the Gambro BCT Apheresis Systems. Vista Information System also helps improve donor utilization by optimizing a procedure based donor parameters, blood center guidelines and needs and only collecting the blood components a donor is qualified to donate.