



Terumo BCT, Inc.
Attention: Ms. Kelsey Stevenson
10811 West Collins Ave
Lakewood, CO 80215-4498

Re: BK150228
Trade Name: Vista Information System Version 4.0
Regulation Number: 21 CFR 864.9175
Regulation Name: software, blood bank, stand alone products.
Regulatory Class: Class II
Product Code: MMH
Dated: August 24, 2015
Received: August 24, 2015

Dear Ms. Stevenson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Richard J. Davey, MD
Director
Division of Blood Components and Devices
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

Enclosure:
Indications For Use

Indications for Use

510(k) Number: BK150228

Device Name: Vista Information System Version 4.0

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
 - Historic trend review of donor vital signs information
 - 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Blood Research and Review

Division Sign-Off
Office of Blood Research and Review