May 22, 2019

Terumo BCT, Inc.
Attention: Ms. Brittany Grochala
10811 West Collins Avenue
Lakewood, CO 80215-4415

Re:	BK190332
Trade/Device Name:	Trima Accel Automated Blood Collection System
Regulation Number:	21 CFR 864.9245
Regulation Name:	Automated blood cell separator
Regulatory Class:	Class II
Product Code:	GKT
Dated:	March 21, 2019
Received:	March 22, 2019

Dear Ms. Grochala:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety

reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, 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: BK190332

Device Name: Trima Accel Automated Blood Collection System

Indications for Use:

The Trima Accel system is an automated blood cell separator intended for use in collecting blood components for later transfusion into patients.

Depending on the disposable tubing set used, the Trima Accel system has been cleared to collect:

- Double ACD-A/AS-3 Red Blood Cells (leukocytes reduced or not leukoreduced)

Or the following products alone or in combination:

- ACD-A/AS-3 Red Blood Cells
- ACD-A/AS-3 Red Blood Cells, Leukocytes Reduced utilizing an integrated filter (TLR gravity drain filter or Auto RBC filter)
- Platelets Pheresis, Leukocytes Reduced (single, double, or triple units)
- Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (Isoplate or InterSol) (single, double, or triple units)
- Plasma for Fresh Frozen Plasma and Fresh Frozen Plasma, Leukocytes Reduced
- Plasma for Plasma Frozen Within 24 Hours After Phlebotomy (PF24) and Plasma Frozen Within 24 Hours After Phlebotomy, Leukocytes Reduced
- Plasma for Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24) and Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy, Leukocytes Reduced
- Source Plasma

Storage of RBCs Collected on the Trima Accel system

- Adequate studies have not been performed to evaluate the effect of gamma irradiation or freezing on the quality of ACD-A/AS-3 red blood cell products (RBCs) collected with gravity drain leukoreduction process (TLR filter) on the Trima Accel system.
- Studies have not been performed to support gamma irradiation or freezing of ACD-A/AS-3 RBCs collected with an integrated in-line RBC leukoreduction filter(s) (Auto RBC filter) on the Trima Accel system.

Storage of Platelets Collected on the Trima Accel system

- Platelets Pheresis may be manufactured from products that do not meet leukocyte reduction product standards. Platelets Pheresis, Leukocytes Reduced, Platelet Additive Solution (Isoplate or InterSol) may be further process (e.g., irradiated, divided). Platelets Pheresis, Platelet Additive Solution (Isoplate or InterSol) may not be manufactured from products that do not meet leukocyte reduction product standards.
- The storage conditions of the Trima Platelet bag (ELP bag) have been verified for storage up to 7 days post-collection in 100% Plasma and up to 5 days in Isoplate (PAS-F) or InterSol (PAS-C) solutions.
- Additionally, for storage up to 7 days, every product must be tested with a bacterial detection device cleared by FDA and labeled as a “safety measure.”

- The Trima Blood Component Sampling Assembly, which is either integrated into the disposable tubing sets or available as an accessory for sterile connection, is intended to allow aseptic removal of a sample from the platelet bag for subsequent bacterial or other applicable testing. The Sampling Assembly does not have contact with blood fluids that are reinfused to a donor or patient.

Storage of Plasma Collected on the Trima Accel system

- Fresh Frozen Plasma and Fresh Frozen Plasma, Leukocyte Reduced must be prepared and placed in a freezer at -18 °C or colder within 8 hours of phlebotomy.
- Plasma Frozen Within 24 Hours After Phlebotomy (PF24) and Plasma Frozen Within 24 Hours After Phlebotomy, Leukocytes Reduced must be stored at 1 °C to 6 °C within 8 hours of phlebotomy and placed in a freezer at -18 °C or colder within 24 hours of phlebotomy and is indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.
- Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy (PF24RT24) and Plasma Frozen Within 24 Hours After Phlebotomy Held At Room Temperature Up To 24 Hours After Phlebotomy, Leukocyte Reduced can be stored at room temperature for up to 24 hours after phlebotomy. Product must be placed in a freezer at -18 °C or colder within 24 hours of phlebotomy and is indicated for replacement of non-labile clotting factors. This product is not equivalent to Fresh Frozen Plasma.

Rx only.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off, Office of Blood Research and Review