July 27, 2023

Terumo BCT
Attention: Jennifer Burton
10811 West Collins Avenue
Lakewood, CO 80215

Re:

STN:	BK230838
Trade/Device Name:	IMUGARD WB PLT Platelet Pooling Set
Regulation Number:	21 CFR 864.9100
Regulation Name:	Empty container for the collection and processing of blood and blood components
Regulatory Class:	Class II
Product Code:	KSR

STN:	BK230843
Trade/Device Name:	Reveos® Automated Whole Blood Processing System
Regulation Number:	21 CFR 864. 9245(b)
Regulation Name:	Separator, Semi-Automated, Blood Component
Regulatory Class:	Class I
Product Code:	MYY
Dated:	April 28, 2023
Received:	April 28, 2023

Dear Jennifer Burton:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 these devices, subject to the general controls provisions of the Act. Although this letter refers to your products as a devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices 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 devices comply 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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: BK230838

Device Name: IMUGARD WB PLT Platelet Pooling Set

Indications for Use:

IMUGARD WB PLT Platelet Pooling Set is intended to be used to leukocyte-reduce, pool and store whole-blood-derived platelets. For platelets prepared through manual methods, leukoreduction and pooling occur on Day 1, the day after whole blood collection and processing, with subsequent platelet storage up to Day 7 in the Terumo BCT ELP storage bag when used with FDA-cleared or approved bacterial detection tests. For platelets prepared by the Reveos® Automated Blood Processing System, leukoreduction and pooling occur on Day 1 or Day 2, with subsequent platelet storage up to Day 7 in the Terumo BCT ELP storage bag when used with FDA-cleared or approved bacterial detection tests. Additionally, for platelet units stored past 5 days and through 7 days, every pooled platelet product must be tested with a bacterial detection device cleared by FDA and labeled as a "safety measure."

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 (OBRR)

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Division Sign-Off
Office of Blood Research and Review

Indications for Use

510(k) Number: BK230843

Device Name: Reveos® Automated Whole Blood Processing System

Indications for Use:

The Reveos device is intended to automatically separate units of whole blood into blood components.

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 (OBRR)

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Division Sign-Off
Office of Blood Research and Review