November 1, 2018

Terumo BCT, Inc.
Nicholas Wong
Sr. Regulatory Affairs Specialist
10811 West Collins Avenue
Lakewood, CO 80215

Re: K181049
Trade/Device Name: Spectra Optia® Apheresis System
Regulatory Class: Unclassified
Product Code: LKN
Dated: October 1, 2018
Received: October 2, 2018

Dear Nicholas Wong:

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 (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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Carolyn Y. Neuland -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181049

Device Name
Spectra Optia® Apheresis System

Indications for Use *(Describe)*
The Spectra Optia® Apheresis System, a blood component separator, may be used to perform therapeutic plasma exchange.

The Spectra Optia® Apheresis System, a blood component separator, may be used to perform Red Blood Cell Exchange (RBCX) procedures for the transfusion management of Sickle Cell Disease in adults and children.

The Spectra Optia® Apheresis System, a blood component separator, may be used to reduce White Blood Cells for patients with leukocytosis at risk for leukostasis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TERUMOBCT

510(k) Summary

I. SUBMITTER

Owner/Manufacturer: Terumo BCT, Inc.
10811 W. Collins Avenue
Lakewood, Colorado 80215
Phone: 877-339-4228

Contact Person: Nicholas Wong
Sr. Regulatory Affairs Specialist
Phone: 303-239-2384
Fax: 303-231-4756

Date Prepared: April 19th, 2018

II. DEVICE

Trade Name of Device: Spectra Optia® Apheresis System
Common or Usual Name: Apheresis Device or System
Regulation Number: N/A
Regulation Name: N/A
Classification Name: N/A
Regulatory Class: Unclassified
Product Code: LKN

III. PREDICATE DEVICE

Spectra Optia® Apheresis System, K172590
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Spectra Optia® Apheresis System has been cleared for the following therapeutic apheresis, cell collection and cell processing procedures:

- Therapeutic Apheresis Procedures:
  - Therapeutic Plasma Exchange (TPE) – K071079, K153601
  - Red Blood Cell Exchange (RBCX) – K132429, K153601
  - White Blood Cell Depletion (WBCD) – K172590
- Collection/Processing Procedures (cleared by CBER):
  - Mononuclear Cell (MNC) Collection – BK120012 & BK150251
  - Granulocyte Collection – BK130065
  - Bone Marrow Processing – BK140191

The Spectra Optia® Apheresis System is an automated centrifugal system that separates whole blood into its cellular and plasma components. The cleared system is comprised of three major subsystems:

1. the apheresis machine itself (centrifuge, centrifuge filler, pumps, valves, computerized safety and control systems, etc.)
2. a sterile, single-use, disposable blood tubing set
3. embedded software

The modifications described in this submission are those required to resolve current obsolescence issues for various electronic components found within the Spectra Optia equipment.

V. INTENDED USE/INDICATIONS FOR USE

The intended use is unchanged as a result of this modification and is identified below:

The Spectra Optia® Apheresis System, a blood component separator, may be used to perform therapeutic plasma exchange.

The Spectra Optia® Apheresis System, a blood component separator, may be used to perform Red Blood Cell Exchange (RBCX) procedures for the transfusion management of Sickle Cell Disease in adults and children.

The Spectra Optia® Apheresis System, a blood component separator, may be used to reduce White Blood Cells for patients with leukocytosis at risk for leukostasis.

VI. TECHNOLOGICAL COMPARISON

The proposed modification does not in any way change the system's fundamental scientific technology or principle of operation; that is, the separation of blood into its components using centrifugation.

VII. PERFORMANCE DATA

A summary of the verification testing and a summary of the validation testing was presented to show that the modified device met all the performance requirements and that the subject device is as safe and performs as well as the predicate device.

VIII. CONCLUSIONS

Based on the verification and validation tests performed on the Spectra Optia Apheresis System with the new electrical components, this system is as safe and effective as the legally marketed predicate device. The information provided in the 510(k) demonstrates that the Spectra Optia Apheresis System is substantially equivalent to the identified predicated device.