February 5, 2019

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

Re: K183081
Trade/Device Name: Spectra Optia® Apheresis System
Regulatory Class: Unclassified
Product Code: LKN
Dated: November 29, 2018
Received: November 30, 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)*
K183081

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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510(k) Summary – K183081

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: January 22nd, 2019

II. DEVICE

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

III. PREDICATE & REFERENCE DEVICE

Table 1: Predicate & Reference Device Information

Device	Product Code	Trade Name of Predicate Device	Manufacturer and 510(k) Holder	510(k) Clearance Number
Predicate	LKN	Spectra Optia Apheresis System	Terumo BCT	K172590
Reference	LKN	Spectra Optia Apheresis System	Terumo BCT	K132429
Reference	LKN	Spectra Optia Apheresis System	Terumo BCT	K131744

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 modification described in this submission introduces a new software version to the Spectra Optia® Apheresis System. The current release is Version 11.3 which was cleared in K153601. The new software version is Version 12 and introduces the following new features:

- Data Management Support,
- Network Support,
- Enhancements to existing protocols including the ability to run the Red Blood Cell Exchange procedure in single-needle mode,
- General Software Maintenance Updates

V. INTENDED USE/INDICATIONS FOR USE

The intended use is unchanged as a result of the new 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

A comparison between the predicate device and the subject device is provided in the following table.

Table 2: Device Comparison Table – Subject Device Compared to Predicate Device

Attribute/Feature of Subject Device	Comparison to Predicate Device
Intended Use	***Compared to the Predicate Device:*** Same. The modifications described in this submission do not alter the intended use of the device. See section V. above for the full intended use statement.
Essential Technology	***Compared to the Predicate Device:*** Same. The modifications described in this submission do not alter the essential technology of the Spectra Optia Apheresis System. It continues to

	be a centrifuge-type therapeutic apheresis device that separate whole blood into its various components.
Hardware or "Equipment"	***Compared to the Predicate Device:*** Same. The modifications described in this submission do not impact the hardware or "equipment" of the Spectra Optia Apheresis System.
Disposable Tubing Set	***Compared to the Predicate Device:*** Same. The modifications proposed with the subject device does not impact any of the previously cleared disposable tubing sets. Version 12 Software allows for the option to switch to single-needle mode for a Red Blood Cell Exchange Procedure as compared to a dual needle procedure originally cleared under K132429. The Exchange set (K141938) and a Single-Needle Connector (K131744) is all that is required.
Software	***Compared to the Predicate Device:*** The Spectra Optia Apheresis system continues to have the same underlying architecture and base software, and are implemented using the same control, safety, and automated process control subsystems. The predicate device is currently utilizing Version 11.3 software. The modifications proposed with the subject device introduces a new version of Software (Version 12), modifications include: 1) data management and network support, 2) enhancements to existing protocol (allowing for the Red Blood Cell Exchange Procedure to be run in single-needle mode), and 3) general software maintenance updates.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Table 3: Performance Testing

Type	Method	Outcome
Software	The Spectra Optia system software development and verification followed a life-cycle approach. The software testing and verification activities included design reviews, hazard analysis, code reviews and software testing. Software tests included safety tests, functional tests and reliability tests. Testing also included normal, as well as limit and failure conditions.	All software testing was complete and all testing indicates that the software meets the required functionality.
Specification Testing	System requirements were reviewed for impact by the modification to the new software. Verification testing was conducted on new and existing impacted lower-level requirements. Validation testing including testing impacted user needs. Additionally, Human Factors testing was performed to support the changes introduced in the new software release. The single-needle functionality was supported with a simulated-patient laboratory study evaluating varying performance measures across the multiple RBCX Procedure Types. A clinical overview report was also performed summarizing clinical evidence supporting safety and effectiveness of Red Blood Cell Exchange Performed on the Spectra Optia® Apheresis System Using Single-Needle Access.	The system performed according to its design specifications and Spectra Optia Version 12 has been found to be safe and effective for the intended users, user, and use environments

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VIII. CONCLUSIONS

Based on the performance data provided on the subject device, the Spectra Optia® Apheresis System with Version 12 software is substantially equivalent to the legally marketed predicate device, the Spectra Optia® Apheresis System with Version 11.3 software.