March 2, 2018

Terumo BCT, Inc.
Nicholas Wong, RAC
Sr. Regulatory Affairs Specialist
10811 W. Collins Avenue
Lakewood, Colorado 80215-4415

Re: K172590
Trade/Device Name: Spectra Optia® Apheresis System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: January 31, 2018
Received: February 1, 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172590

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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In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary for the Spectra Optia® Apheresis System is provided below.

1. SUBMITTER

Terumo BCT, Inc.
10811 W. Collins Avenue
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Phone: 720-480-6702

Contact Person: Nicholas Wong
Title: Sr. Regulatory Affairs Specialist
Phone: 303-239-2384
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Date Prepared: March 2, 2018

2. 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

3. PREDICATE AND REFERENCE DEVICE

Predicate Device: Terumo BCT's COBE® Spectra Apheresis System (K831004)

Reference Device: Terumo BCT's Spectra Optia® Apheresis System (K153601)

4. DEVICE DESCRIPTION

As a whole, 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
- 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

This 510(k) involves no change in the components (design or material) of the Spectra Optia® Apheresis System. Instead, the purpose of this 510(k) is to expand the indications for use to include reduction of White Blood Cells (WBCs) for patients with leukocytosis at risk of leukostasis.

During a WBCD procedure, the system pumps the patient's blood into the tubing set and spins the centrifuge at a speed required to target the optimal packing factor (4.5) for a WBCD procedure using an anticoagulant (ACD-A). The Automated Interface Management (AIM) system adjusts the flow rate of the plasma pump to control the concentration of cells that flow through the collect port. This step can be controlled via the collection preference. When the AIM system detects cells in the collect port, the system sounds a tone, the collect valve moves into the collect position, and the collect pump pumps the cells into the collection bag. The plasma pump pumps plasma out of the channel and into the reservoir. The red blood cells (RBC) are pushed out of the channel and into the reservoir, where they combine with the plasma for return to the patient.

5. INTENDED USE/INDICATIONS FOR USE

The Spectra Optia® Apheresis System has been previously cleared for therapeutic plasma exchange (TPE) and Red Blood Cell Exchange (RBCX). This 510(k) involves an expansion of the indications for use, which is reflected below in italics.

Indication Statement:

> 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 of leukostasis.*

Compared to the predicate, COBE Spectra, the device has the same intended use as a blood component separator. The predicate COBE Spectra device was previously cleared for a specific indication of therapeutic cellular depletion. The proposed modification to the indications for use falls within the general cleared indication of the predicate device.

6. TECHNOLOGICAL COMPARISON

Spectra Optia System simplifies the WBC Depletion Protocol when compared to the predicate system with the use of on-screen guidance and an integrated cassette tubing set design. The Spectra Optia System key performance characteristics determined by laboratory evaluation for the WBC Depletion Protocol when compared to the predicate are:

- A Mean Collection Efficiency for WBC of 83.6% (±18.8%) compared to 70.6% (±12.9%)
- Can collect under a wide range of patient/procedural parameters including hematocrit, inlet flow rate, and collect flow rate
- Allows operators to perform other tasks during the procedure as the system continuously monitors and adjusts the interface

The technology for the Spectra Optia System is not identical to the predicate device; however, the differences do not impact on substantial equivalence.

7. PERFORMANCE DATA

Both bench and clinical data were provided in support of substantial equivalence of the modified indications for use for the Spectra Optia® Apheresis System.

7.1. Bench Testing

Terumo BCT performed verification bench testing that demonstrates that the system works as intended. Testing was done in comparison to the predicate device.

The testing was performed over a broad range of operational setting/parameters using blood products that vary with respect to clinical conditions for WBC content. The testing demonstrated that the Spectra Optia® WBC Depletion Protocol is non-inferior to the predicate the COBE Spectra WBC Depletion Protocol. The software, filler, and disposable are able to reduce WBCs effectively over a wide range of patient/procedural parameters including hematocrit (HCT), inlet flow rate (Qin), and collect flow rate.

7.2. Clinical Data

Clinical testing of the Spectra Optia® Apheresis System WBC Depletion Protocols was performed.

The WBC Depletion clinical study was a multicenter, single-arm, retrospective data collection study to evaluate the routine-use performance and safety of WBC Depletion conducted with the Spectra Optia® Apheresis System. Clinical routine-use data were collected retrospectively from 58 WBC Depletion procedures performed on 43 subjects.

7.2.1. Location of Study

The retrospective study was conducted at 3 sites in Europe: UZ Leuven, Belgium, Institute for Transfusion Medicine and Immunohematology, Frankfurt, Germany and Saint Istvan and Saint Laszlo Hospital, Budapest, Hungary.

7.2.2. Primary Effectiveness Endpoint

The primary effectiveness endpoint of the study included evaluation of Device Performance Parameters including percent decrease in WBC count in subject blood following apheresis procedures and percent of processed WBCs collected, i.e., collection efficiency (CE) for WBC achieved by the Spectra Optia® Apheresis System.

7.2.3. Primary Safety Endpoint

The primary safety endpoint consisted of an evaluation of adverse events (AEs) during the WBC Depletion apheresis procedure for up to 24 hours post-procedure.

7.2.4. Effectiveness

Data were collected for 43 subjects who underwent a total of 58 WBC Depletion procedures at 3 sites.

The criteria for WBC Depletion are determined by the patient's WBC counts and clinical status. The mean percent decrease in subject WBC counts post-procedure was 54.7% (SD: 21.3%). The observed mean percent decrease in WBC count was consistent with American Society for Apheresis (ASFA) guidelines, where a single leukocytapheresis procedure is reported to reduce WBC count by 30% to 60%.

The CE of the WBC Depletion procedures as measured from the waste bag contents was 58.7% (SD: 16.1%).

7.2.5. Safety

The frequency and type of AEs observed is reflective of the very sick leukemia patient population in which WBC Depletion procedures are typically performed, with no observed safety signals associated with the Spectra Optia® device. The most common Treatment Emergent Adverse Events (TEAEs) (i.e., those reported for > 5% of subjects) were related to hematology or serum chemistry abnormalities, which are expected AEs within this leukemia patient population, including thrombocytopenia and/or decreased platelet count, anemia, hypocalcemia, and hypokalemia. No serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) were reported. One subject (2.3%) terminated the WBC Depletion procedure prematurely due to a moderate TEAE of vascular access complication.

7.2.6. Summary

The data collected within this study indicated that WBC Depletion procedures using the Spectra Optia® Apheresis System were well tolerated and effective at decreasing circulating WBCs in a sick leukemia patient population, as evaluated by percent decrease in WBC count, CE for WBC, and AEs during and within 24 hours post-procedure. Percent decrease in WBC count observed in the study was comparable to results reported in the literature.

8. CONCLUSIONS

Based on the non-clinical and clinical testing, the proposed Spectra Optia Apheresis System with the modified indication for use has been determined to be as safe and effective as the legally marketed predicate device and therefore, may be found substantially equivalent.