DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 11, 2015

Terumo BCT, Inc.
Nicholas Wong
Regulatory Affairs Specialist
10811 West Collins Avenue
Lakewood, CO 80215-4415

Re: K151368
Trade/Device Name: Spectra Optia Apheresis System
Regulation Number: None
Regulation Name: Separator, Automated, Blood Cell And Plasma, Therapeutic
Regulatory Class: Unclassified
Product Code: LKN
Dated: August 11, 2015
Received: August 12, 2015

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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)*

K151368

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.

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.

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510(k) Summary

I. SUBMITTER

Owner/Manufacturer: Terumo BCT, Inc.
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Contact Person: Nicholas Wong
Regulatory Affairs Specialist
Phone: 303-239-2384
Fax: 303-231-4756

Date Prepared: May 20, 2015

II. DEVICE

Trade Name of Device: Spectra Optia® Apheresis System
Common or Usual Name: Apheresis Device or System
Classification Name: Automated Blood Cell Separator, Therapeutic
Regulatory Class: Unclassified
Product Code: LKN

III. PREDICATE DEVICE

Spectra Optia Apheresis System - Exchange Set (K071079)
&
Reference Device: Spectra Optia Apheresis System (K141938)

IV. DEVICE DESCRIPTION

A. Device Characteristics

The Spectra Optia Apheresis System is comprised of three subsystems: the apheresis machine (or equipment), embedded software, and a single-use disposable blood tubing set. The modifications described in this submission enhance the disposable set's safety during therapeutic plasma (TPE) and red blood cell exchange (RBCX) procedures and usability with the optional Wireless Solution.

Spectra Optia Machine and Embedded Software:
The Spectra Optia Apheresis System is an automated, centrifugal, blood component separation device that uses pumps, valves and sensors to control and monitor a disposable, plastic, extracorporeal circuit, during therapeutic apheresis procedures. The system's embedded software controls pump flow rates and centrifuge speed to establish and maintain the required plasma/cellular interface, and ensure patient safety.

Disposable Blood Tubing Set:
The disposable Spectra Optia Exchange Set (Catalog No. 12220) is provided sterile and is intended for single-use only. The set is invasive, in that patients are connected to the disposable using a needle or other blood access device (catheter, port, etc.) during the procedure. The patient's blood comes into direct contact with the biocompatible materials that comprise the set. Key components of the set include the [1] centrifuge channel (inside which the patient's blood is separated into its components), [2] the plastic cassette that integrates the tubing/defines the fluid path for ease of installation and use and, [3] the pre-attached waste bag into which the unwanted blood component is collected. Terumo BCT is replacing the standard spike located on the anticoagulant line with a unique luer that is not compatible with any other connection on the set to decrease operators from connecting the wrong solutions bag.

B. Environment of Use
The Spectra Optia Apheresis System is operated in a hospital or clinic environment. Exchange Sets are used with the TPE & RBCX protocols.

The operation of the Spectra Optia system is performed by professionally-trained apheresis operators. Operators are commonly trained on the principles of apheresis by their organization. Operators of the device have a variety of backgrounds and professional training, and the primary users are expected to be nurses or qualified laboratory technicians.

C. Device Description
Wireless Solution:
The Spectra Optia Wireless Solution includes both a mounting system and a wireless appliance. No modifications were made to the Spectra Optia device in support of the wireless solution. Neither the intended use of the device nor the intended use environment of the Spectra Optia has been modified in support of the wireless solution option.

AC Connection System – 12220: Exchange Set with AC Connection
The Exchange tubing set, catalog number 12220, is identical to the previously cleared Exchange set, catalog number 10220 (K141938), except the AC spike port is replaced with the new unique AC luer connector. The AC line is used to carry anticoagulant from the AC container to the inlet line manifold.

AC Connection System – AC Connection Adapter
The Anticoagulant (AC) Connection Adapter, catalog number 11221, is used to connect an apheresis tubing set that has a luer connector to an anticoagulant solution container that has a spike receptor. The anticoagulant solution container can be collapsible, such as a bag, or hard-sided, such as a bottle. The Anticoagulant Connection Adapter is sterilized by Ethylene Oxide, for single use only, and includes the following components:

1. AC (anticoagulant) connector with end cap: used to connect to the luer connector on the AC line of a tubing set
2. Vent: used when connecting to a hard-sided AC container
3. Spike with end cap: used to connect to the spike receptor on the AC container

D. Materials of Use

Since Terumo BCT, Inc. has obtained clearance for the Apheresis Machine and the Standard Filler (K071079), the discussion of materials of use is limited to the Exchange tubing set, catalog number 12220, and Anticoagulant (AC) Connection Adapter, catalog number 11221. The Exchange tubing set, 12220, and Anticoagulant (AC) Connection Adapter, catalog number 11221 makes use of existing materials that are used in several different marketed product lines, including COBE Spectra and Spectra Optia. These materials include plasticized polyvinyl chloride (PVC) for tubing, copolyester, acrylonitrile butadiene styrene (ABS), and polycarbonate; these materials are medical grade and are deemed suitable for human blood and blood components. The materials used in the Exchange tubing set, 12220, and Anticoagulant (AC) Connection Adapter, catalog number 11221 that do not make blood contact include low density polyethylene and high density polyethylene.

E. Key Performance Specifications/Characteristics of the Device

Wireless Solution:

The wireless appliance provides a way for Terumo BCT devices equipped with Ethernet to securely connect, via WPA2 encryption, to a wireless network that complies with IEEE 802.11 b, g, and n. The Spectra Optia device meets the applicable Medical Electrical System requirements and the EMC Standards when connected to the following wireless appliances:

- D-Link® Wireless N Range Extender (DAP-1360)
- Silex SX-BR-4600WAN
- D-Link® DAP-1665 Wireless AC1200 Dual Band Access Point

If a customer would like to use a wireless appliance with the Spectra Optia other than those outlined above, the wireless appliance must meet specific specifications indicated in Table 5-1.

Table 5-1 - Wireless appliance specifications

Characteristic	Specification
Maximum allowable dimensions	Height: 14.9 cm (5.875 in) Width: 15.2 cm (6.00 in) Depth: 3.8 cm (1.5 in)
Input voltage range	100 V AC to 240 V AC, 50/60 Hz
Input power maximum	200 VA
Operating temperature range	0 °C to 40 °C (32 °F to 104 °F) If the selected wireless appliance has an operating temperature range outside of the specified range, your facility must validate the temperature range of the wireless appliance.
Storage temperature range	0 °C to 60 °C (32 °F to 140 °F)
Network interface	Have at least one RJ45 Ethernet connector that supports 10 base-T Ethernet communication
Wireless standard	IEEE 802.11b, IEEE 802.11g, and IEEE 802.11n
Security protocol	WPA2

The wireless appliance can be used for several purposes, depending on the device configuration. Table 5-2 describes possible functions of the wireless appliance. The table also includes information on the criticality to operation of the Spectra Optia device if the function cannot be

performed due to a problem with the wireless appliance or the network. Note- wireless technology is not used for transmission, reception, or processing involving alarms signals.

Table 5-2 - Wireless Functions

Function	Description
Transmits reports from the device to either a printer or a customer computer	Reports are generated by the Terumo BCT device for each procedure. The format and content of these reports depends upon the type of Terumo BCT device and its configuration. These reports are for customer use only.
Transmits device log files (dlogs) from the device to the Cadence® Data Collection System	Dlogs are created for each procedure and contain information about Terumo BCT device performance during the procedure. Dlogs can be used for monitoring and diagnostic purposes.

V. INTENDED USE

The Spectra Optia Apheresis System, a blood component separator, may be used to perform therapeutic plasma and red blood cell exchange procedures.

VI. INDICATIONS FOR USE

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

The Indications for Use statement for the Spectra Optia Apheresis System is identical to predicate device.

VII. TECHNOLOGICAL COMPARISON

The modified Spectra Optia Exchange Set to include the unique Anticoagulant Connector and the Anticoagulant Connection Adapter 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.

The Wireless Network Solution also 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.

VIII. PERFORMANCE DATA

The following performance testing was submitted in support of a determination of substantial equivalence between the subject and predicate device. A summary of the performance testing is presented in Table 5-3 below. Test data demonstrates that the device met all performance requirements and that the subject device is as safe, as effective, and performs as well or better than the predicate device.

Table 5-3: Summary of Performance Studies

Test Name	Purpose of Study	Result
Verification Summary Report for Wireless Network Solution on Optia	To summarize the verification completed for the Wireless Network Solution	Pass
Design Verification Report for Apheresis Safety AC Connection Project	To summarize the verification testing for the AC Connection project.	Pass

A. Mechanical Testing

A variety of physical and mechanical testing was conducted for the Exchange tubing set, catalog number 12220, and Anticoagulant Connection Adapter, catalog number 11221. The results are all passing within acceptance criteria.

In addition to appropriate EMC immunity and emissions tests and coexistence testing, performance verification testing was conducted to demonstrate safety and effectiveness of the wireless technology

B. Biocompability Testing

The biocompatibility evaluation for the Exchange tubing set, catalog number 12220, and Anticoagulant Connection Adapter, catalog number 11221, was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

C. Electrical Safety and Electromagnetic Compatibility (EMC) Testing

EMC Immunity and emissions tests and coexistence testing were conducted on the Wireless Appliance for the Spectra Optia Device. The purpose of the tests was to give a level of confidence that this product complied with selected requirements of IEC/EN 60601-1-2: 2007 when configured with three different Ethernet routers. The results are all passing within acceptance criteria.

D. Software Verification and Validation Testing

Software verification and validation testing for Version 11.2 software was conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." This content has not been modified since it was cleared by FDA in BK140191.

E. Sterility Testing

Products are validated to ensure that they are not released until acceptance criteria are met according to the requirements outlined in ANSI/AAMI/ISO 10993-7:2008. When sterilized with the validated ethylene oxide cycle, the product has a sterility assurance level of $< 10^{-6}$. When outgassed using the validated process, the Exchange tubing set, catalog number 12220, and Anticoagulant Connection Adapter, catalog number 11221, meet the residual limits according to predetermined acceptance criteria. Product sterilization has been successfully demonstrated and is similar to the Spectra Optia family of disposables.

F. Stability/Shelf Life Testing

The shelf life of the Exchange tubing set, catalog number 12220, and Anticoagulant Connection Adapter, catalog number 11221, was determined to be 2 years. Terumo BCT, Inc. evaluated the overall configuration and materials, their packaging and sterilization process.

IX. CONCLUSIONS

Based on the non-clinical tests performed on the proposed Spectra Optia Apheresis System Exchange Set and Wireless Network Solution, the device is substantially equivalent to the legally marketed predicate device.