

DEC - 6 2013

510(k) Summary

Owner/Manufacturer: Terumo BCT, Inc.
10811 W. Collins Avenue
Lakewood, Colorado 80215

Contact Person: Tina O'Brien
Senior Regulatory Affairs Specialist
Phone: (303) 239-2082

Date of Summary Preparation: August 2, 2013

Trade Name: Spectra Optia[®] Apheresis System

Common Name: Apheresis System

Classification Name: Automated Blood Cell Separator

Product Code: LKN

Predicate Device: Spectra Optia Apheresis System

Device Description: The Spectra Optia Apheresis System is a centrifugal system that separates whole blood into its cellular and plasma components. The device is comprised of three major sub-systems: (1) the apheresis machine itself (centrifuge, pumps, valves, etc.), (2) sterile, single-use, disposable tubing sets and, (3) embedded software.

Modifications to the disposable Exchange Set and embedded software have been made to enable Red Blood Cell Exchange (RBCx) procedures on the Spectra Optia system.

Intended Use:

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic apheresis applications, and may be used to perform Red Blood Cell Exchange, Depletion, and Depletion/Exchange (RBCX) procedures.

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.

Technological Comparison:

The system's base technology is not changed by the introduction of the RBCx protocol.

Discussion of Non-clinical Data:

The modified Spectra Optia system software was verified through a variety of verification testing; including Functional, Reliability, Usability, Exploratory, and Robustness.

Discussion of Clinical Data:

A prospective, multi-center, single-arm, open-label study was conducted to demonstrate that the Spectra Optia's RBCx protocol could consistently achieve the target HbS in the target population as prescribed by the physician. The study resulted in all primary endpoints being met with no serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) reported.

Substantial Equivalence:

Provided below is a summary of substantial equivalence.

Table 1: Spectra Optia system vs. COBE Spectra

	<i>Spectra Optia system (Subject Device)</i>	<i>COBE Spectra system (K831004)</i>
Intended Use	Therapeutic Plasma Exchange and Red Blood Cell Exchange	Multiple therapeutic apheresis procedures, including Red Blood Cell Exchange
Essential Technology	Both the Spectra Optia and COBE Spectra systems are automated blood cell separators achieving their essential function (the separation of blood cells and plasma) through centrifugation.	
Software	Software algorithms underlying the red blood cell exchange procedures on both the Spectra Optia and COBE Spectra systems are controlled by the same equations.	
Performance	In both a "simulated-use" laboratory validation study and human clinical trial, Spectra Optia's RBCx protocol was found to perform the same as the COBE Spectra RBCx protocol, with respect to the system's ability to achieve patient hematocrit targets and to maintain patient fluid balance.	



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

Terumo BCT, Inc.
Tina O' Brien
Sr. Regulatory Affairs Specialist
10811 West Collins Avenue
Lakewood, CO 80215

Re: K132429
Trade/Device Name: Spectra Optia[®] Apheresis System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: November 1, 2013
Received: November 4, 2013

Dear Tina O' Brien,

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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

TERUMOBCT

**Spectra Optia[®] Apheresis System
Red Blood Cell Exchange (RBCx)
Traditional 510(k) Submission**

Indications for Use

510(k) Number (if known): K132429

Device Name: **Spectra Optia[®] Apheresis System**

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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)