NOV 19 2010

510(k) Summary

Owner/Manufacturer:	CaridianBCT, Inc. 10811 W. Collins Avenue Lakewood, Colorado 80215
Contact Person:	Patti Arndt Senior Regulatory Affairs Specialist Office Phone: (303) 231-4823
Date of Summary Preparation:	October 18, 2010
Trade Name:	Spectra Optia® Apheresis System
Common Name:	Therapeutic Apheresis System
Classification Name:	Separator, Automated, Blood Cell and Plasma, Therapeutic
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 system is used therapeutically to remove and exchange blood plasma in patients who suffer from adverse hematologic and other conditions.

The system includes a disposable Exchange Set through which the patient's blood passes, and a machine that controls the separation of blood into its components and monitors the exchange procedure for patient safety. The Spectra Optia machine and its embedded software have been modified to include and support a return line air detector, respectively. The return line air detector serves as a backup air detection system and represents an enhancement to the system's overall safety profile. This additional sensor actively monitors the return line and detects the presence of air, prior to its reaching the patient. In the unlikely event that the extracorporeal circuit is improperly anticoagulated and clotted material in the disposable set interferes with the system's primary air detection sensors, the modified device "alarms" when air is detected and instructs the operator to clear the return line. Because the operator must clear the line before the apheresis procedure can be continued, patients are protected from receiving potentially unsafe quantities of air - even when the operator has sub-optimally anticoagulated the circuit. In the further unlikely event that the operator disregards the system's instructions to clear air in the line, the software safely terminates the apheresis procedure.

Intended Use:

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic plasma exchange.

Technological Comparison:

The base technology of the Spectra Optia system is not changed by the presence of the return line air detector, and there is no change to the disposable Exchange Set.

The return line air detector is very similar to sensors that are currently used in other parts of the Spectra Optia system, as is the supporting software.

Discussion of Non-clinical Data:

The correct functioning of the return line air detector was verified through the following activities:

- Physical testing of the modified Spectra Optia machine to ensure that the ultrasonic sensor does not interfere with the interaction between the Spectra Optia machine and the disposable Exchange Set.
- Software code reviews and unit tests to ensure that algorithms and other code were written correctly and yield the expected results.
- Integration tests to ensure that the modified software and hardware function correctly.
- Simulated use tests to ensure that the backup air detection system consistently functions as expected.

Discussion of Clinical Data:

Extensive laboratory testing was conducted to verify and validate the functionality and effectiveness of this additional air detection system. Clinical validation data were not necessary, as the modification did not impact the implementation, control, or effectiveness of the system's therapeutic apheresis protocols.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Ms. Patti Arndt
Sr. Regulatory Affairs Specialist
CaridianBCT, Inc.
10811 W. Collins Avenue
LAKEWOOD CO 80215

NOV 19 2010

Re: K103090
Trade/Device Name: Spectra Optia® Apheresis System
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: October 18, 2010
Received: October 19, 2010

Dear Ms. Arndt:

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.

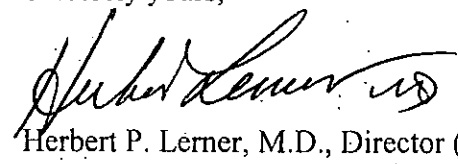
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21CFR 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 19 2010

CaridianBCT

Spectra Optia®Apheresis System
Additional Air Detection System
Special 510(k) Submission

4 Intended Use Use Statement

510(k) Number: K103090

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

Intended Use

The Spectra Optia Apheresis System, a blood component separator, is intended for use in therapeutic plasma exchange.

Prescription Use: **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: **NO** (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)

Carolyn J Neuland for Herb Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K103090