



Food and Drug Administration  
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January 14, 2016

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

Re: K153601  
Trade/Device Name: Spectra Optia Apheresis System  
Regulation Number: None  
Regulation Name: None  
Regulatory Class: Unclassified  
Product Code: LKN  
Dated: December 15, 2015  
Received: December 16, 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,

  
**Herbert P. Lerner -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

## Indications for Use

510(k) Number (if known)

K153601

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## **6 510(K) SUMMARY**

Terumo BCT requests that the attached “Summary” for the Spectra Optia Apheresis System be distributed upon request under the Freedom of Information Act. This report is a summary of the information presented in this 510(k) submission.

## 510(k) Summary

### I. SUBMITTER

Owner/Manufacturer: Terumo BCT, Inc.  
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Contact Person: Nicholas Wong  
Regulatory Affairs Specialist  
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Date Prepared: 12/11/2015

### II. DEVICE

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

### III. PREDICATE DEVICE

Spectra Optia<sup>®</sup> Apheresis System – K151368

This release is a firm initiated recall of the previous software version 11.2 that was submitted in BK140191.

### IV. DEVICE DESCRIPTION

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 impact the embedded software.

*Spectra Optia Machine and Embedded Software:* As described previously (K071079, BK140191, K151368), 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.

### V. INTENDED USE/INDICATIONS FOR USE

The intended use is unchanged as a result of this modification and is identified below:

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

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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.

**VI. TECHNOLOGICAL COMPARISON**

The proposed modification 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 following technological characteristics are identical to that of the predicate device:

- Materials
- Design
- Energy source

**VII. PERFORMANCE DATA**

Version 11.3 is a minor software update limited in scope to mitigate use-errors where operators are able to enter incorrect patient height and weight combinations that would cause a safety concern for the patient. The Version 11.3 software was verified and validated following our design control process. **Table 6-1** below summarizes the Software Verification Type testing that was performed.

**Table 6-1: Executive Summary**

Verification Type	Number of Verifications	Pass	Fail
New / Updated Requirements	110	110	0
Safety Regression Tests	13	13	0
Compatibility (upgrade)	1	1	0
Exploratory	4	4	0
Internal Usability	2	2	0
Reliability	10	10	0

The Version 11.3 Software was validated via Human Factors testing. After completing formative evaluations, a summative study was conducted on twenty-three active Spectra Optia users to evaluate Version 11.3 software in the intended use environment. The study was performed using a software simulator which was functionally equivalent to production software. The summative study was conducted to evaluate the ability of the user to use correct units while entering patient height, weight, and TBV (if applicable) to verify that the data entered was correct. These two tasks, which are also the only identified critical tasks, were successfully completed by all subjects and no performance failures were observed during the study.

**VIII. CONCLUSIONS**

Verification and validation test results demonstrate that the modified software (Version 11.3) of the Spectra Optia Apheresis System performed as designed. This modification to the software is minor and does not impact the intended use of the device or the primary technological characteristics. Terumo BCT, Inc. considers the proposed Version 11.3 software to be substantially equivalent to the previously cleared software Version 11.2 (K151368).