K060482

SEP 28 2006

Exhibit 14

Cytori Celution Cell Concentration Device

510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name: Cytori Therapeutics, Inc.
3020 Callan Road
San Diego, CA 92121

Official Contact: Kenneth K. Kleinhenz
Sr. Director of Regulatory Affairs
Telephone (858) 458-0900
Fax (858) 458-0994

DEVICE NAME

Classification Name: Autotransfusion Apparatus
Trade/Proprietary Name: Cytori Celution™ Cell Concentration Device

ESTABLISHMENT REGISTRATION NUMBER

2031733

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21 CFR 868.5830, Autotransfusion Apparatus devices are defined as a device used to collect and reinfuse the blood lost by a patient due to surgery or trauma. Autotransfusion Apparatus devices are classified as Class II. They have been assigned Product Code CAC.

INTENDED USE

The Cytori Celution™ Cell Concentration Device is indicated for the collection, concentration, washing, and reinfusion of autologous cells collected intraoperatively or postoperatively to obtain concentrated blood cells for reinfusion. Such areas of application may include, but are not limited to, the following:

- General Surgery
- Cardiovascular Surgery
- Orthopedic Surgery
- Vascular Surgery
- Plastic/Reconstructive Procedures
- Obstetric/Gynecologic Surgery
- Neurosurgical Procedures
- Thoracic Surgery
- Transplantation Surgery
- Emergency / Trauma Procedures
- Urology Procedures
- Postoperative Treatment Areas

DEVICE DESCRIPTION

Design Characteristics

The Cytori Therapeutics Celution™ Cell Concentration Device consisting of a centrifuge, blood collection canister, peristaltic pumps, pinch valves, various fault sensors, controller and associated firmware logic, user interface key pad and associated vacuum fluorescent display. The Celution Cell Concentration Device weighs approximately 170 lbs, measures 35 inches x 20 inches with a height of 55 inches, and is equipped with lockable caster wheels for portability in the operating suite. The Celution Cell Concentration Device is used in conjunction with a sterile disposable set that consists of a blood collection canister, a concentration chamber, a waste bag, and associated tubing. The Disposable Set for the Celution Cell Concentration Device is provided in a separate sterile package and installed onto the Celution Cell Concentration Device by the user at the time of use by contacting the tubing with the peristaltic pumps and pinch valves. Various washing solutions are provided by the user and connected to the single-use disposable set through the use of "spike ports" attached to the ends of the tubing. The user is able to choose between large and small volume disposable sets based on the user's needs. The large volume set (190ml chamber size) is referred to as the "Macro" disposable set while the small volume set (70ml chamber size) is referred to as the "Micro" disposable set. The Macro and Micro disposable sets consists of the same essential configuration with respect to tubing, bags, rotating seal, etc., and operate on the same principles of peristaltic pumping of fluids, centrifugation, etc. The Macro and Micro disposable sets differ with respect to their collection chambers and continuous processing capabilities as the 190 ml Macro chamber can processes multiple runs and pump the cellular product to a sample bag while the 70ml Micro chamber can only process one time and must have its contents removed from the chamber with a syringe and needle.

The centrifuge of the Celution Cell Concentration Device concentrates and pellets the cells in the concentration chamber and the peristaltic pumps and associated pinch valves interact with the disposable tubing to remove the supernatant from the pelleted cells and deliver the waste to the waste bag. The Celution Cell Concentration Device then washes the cells by delivering the user-provided washing solutions to the pelleted cells through the use of the same peristaltic pump/tubing interface. Upon completion of the wash cycles, the pelleted cells are them available for use by the physician. The Celution Cell Concentration Device is operated by the user through use of a menu driven program that prompts the user to perform various tasks. The device operates on a user interaction principle through use of the key pad by requiring the user to confirm the completion of prompted tasks before continuing on to the next programmed step. The device also provides positive feedback as there are sensors built into the device to confirm the execution of critical tasks and/or equipment error conditions.

Design Verification Testing
Testing demonstrated that the performance of the Cytori Celution Cell Concentration Device is substantially equivalent to the predicate device as they both yield a blood product that is substantially equivalent with respect to key cellular components. Mechanical and safety testing of the Cytori Celution Cell Concentration Device further demonstrate substantial equivalence to the predicate device with respect to sterility, biocompatibility, stability, durability, reliability, electrical safety, and software validation. Test results indicate that the mechanical properties of the Cytori Celution Cell Concentration Device are substantially equivalent to the mechanical properties of the predicate devices.

EQUIVALENCE TO MARKETED PRODUCT
The Cytori Celution Cell Concentration Device shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to pre-amendment devices: Medtronic Autolog Autotransfusion System (K972894), Dideco Electra (K020647), and Dideco Autologous Blood Management System (K982650).

Indications For Use
The Cytori Therapeutics Celution Cell Concentration Device and the predicate devices share substantially equivalent indications for use with the predicate devices as they all share nearly identical language and are all indicated for washing, concentrating, and processing blood for eventual return to the same patient within the same type of surgical procedures.

Design and Materials
The design and materials of Cytori Celution Cell Concentration Device and the predicate devices (Medtronic Autolog Autotransfusion System, Dideco Electa, and Dideco Autologous Blood Management System) are substantially equivalent as they are all free standing devices that perform the same basic function (collect, wash, and concentrate blood for reinfusion) through use of the like technology (centrifugation, peristaltic pumps, pinch valves, sensor, user interface module, etc.) in combination with multiple sterile, single-use disposable sets that utilize standard medical grade materials and associated tubing, waste bags, collection bags, collection reservoirs, and concentration chambers / bowls. The Cytori Celution Cell Concentration Device is also substantially equivalent to the predicate devices with respect to customer-supplied reagents as they all require and subsequently accommodate customer-supplied washing solutions / reagents used during the cell washing and concentration procedure through use of IV bag hooks / poles, spike ports, etc.

The disposables of the Cytori Celution Cell Concentration Device and the predicated devices are substantially equivalent as they are all sterile, single-use disposable sets that are installed onto the device by the user. Additionally, the Cytori Celution Cell Concentration Device and the predicated devices' disposable sets all utilize substantially equivalent designs of waste bags, collection bags, and blood collection reservoirs interconnected through use of small gauge tubing. The Cytori Celution Cell Concentration Device and the predicated devices all employ a substantially equivalent technology of moving fluids throughout the device's disposable set (e.g., from reservoir to reservoir) through the use of pinch valves that contact the tubing to prevent back flow in conjunction with peristaltic pumps that squeeze / compress the tubing and subsequently roll over the tubing to move the fluids in a specific direction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2006

Cytori Therapeutics, Inc.
c/o Mr. Kenneth K. Kleinhenz
Senior Director of Regulatory Affairs
3020 Callan Road
San Diego, CA 92121

Re: K060482
Celution Cell Concentration Device
Regulation Number: 21 CFR 870.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: August 2, 2006
Received: August 21, 2006

Dear Mr. Kleinhenz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060482

Device Name: Cytori Celution Cell Concentration Device

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- Thoracic Surgery
- Transplantation Surgery
- Emergency / Trauma Procedures
- Urology Procedures
- Postoperative Treatment Areas

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachney

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060482