K092923/52

ADMINISTRATIVE INFORMATION

JAN - 6 2010

Manufacturer Name:	Cytori Therapeutics, Inc. 3020 Callan Road San Diego, CA 92121
Official Contact:	Kenneth K. Kleinhenz Vice President Regulatory Affairs and Quality Assurance Telephone (858) 458-0900 Fax (858) 458-0994

DEVICE NAME

Classification Name:	Suction Lipoplasty System
Trade/Proprietary Name:	Cytori PureGraft 250/PURE System

ESTABLISHMENT REGISTRATION NUMBER

3002642958

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21 CFR 878.5040, Suction Lipoplasty Systems are defined as devices consisting of collection bottles, cannulas, and connecting tubing for use in aesthetic body contouring procedures. Suction Lipoplasty Systems are classified as Class II. They have been assigned Product Code MUU.

INDICATIONS FOR USE

The Cytori PureGraft 250/PURE System is indicated for use in the harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.

DEVICE DESCRIPTION

Design Characteristics

The Cytori PureGraft 250/PURE System is a sterile, single use, closed-loop tubing and bag system intended for delivering adipose tissue back to the same patient for cosmetic and reconstructive surgery applications. Cytori PureGraft 250/PURE consists of collection bags, tubing and syringe adaptors that all have unique connectors and fittings to assure proper assembly. The Cytori PureGraft 250/PURE System is composed of the following components:

Components	Quantity
PureGraft 250mL Bag	1
1.5L Waste Bag with Connection Tubing	1
Inlet Tubing with Spike	1
Luer-lock Syringe Adaptor	2
Toomey Syringe Adaptor	12

The PureGraft 250mL/PURE System may be used in conjunction with an Easel Rack to hold the PureGraft 250 Bag and a Squeegee that applies pressure to the exterior of the PureGraft 250mL Bag to facilitate the movement of excess away from the tissue and into the Waste Bag.

PureGraft 250mL Bag

The PureGraft 250mL Bag is a sterile, single-use, 500mL capacity mixing bag measuring approximately 10" x 6" and consists of 2 filters layered between a polyvinyl chloride (PVC) outer shell and 3 ports on the bottom of the bag. Each port is labeled and unique in design to assure the proper connection is made and to alleviate confusion. The "drain" port contains a male luer fitting, the "inlet" port contains a female swabable luer fitting, and the "tissue" port contains a Toomey syringe adaptor female fitting. The "tissue" port and the "inlet" port are designed as one-way valves to assure that the contents within the PureGraft 250mL Bag are not accidently spilled from the bag. The PureGraft 250mL Bag contains two (2) filters that are continuous within the bag. The first filter is a 1,000 micron filter mesh and the second filter is a 74 micron filter. All materials are medical grade and DEHP free.

Waste Bag with Connection Tubing

The Waste Bag is a sterile, single use, 1.5 liter bag measuring approximately 11" x 8" with a 1/8th inch drain tube measuring 48 inch in length. The drain tube is provided with a pinch clamp on the exterior of the tubing to control the ingress and egress of fluids to and from the Waste Bag. The attached drain tubing contains a luer lock fitting that mates with the male luer lock on the "drain" port of the PureGraft 250mL Bag. All materials are medical grade and DEHP free.

Inlet Tubing with Spike
The Inlet Tubing set is a sterile, single use, 1/8th inch tubing approximately 66 inches in length with a spike for puncturing an IV bag at one end, a male luer at the other and a "Y" port with a one-way luer valve. The Inlet Tubing set is provided with a pinch clamp on the exterior of the tubing to control the flow of fluids. The male luer mates with the female swabable luer fitting on the "inlet" port of the PureGraft 250mL Bag. All materials are medical grade and DEHP free.

Luer-Lock Syringe Adapter
The Luer-Lock Syringe Adapter is a sterile, single use, female / female cylinder measuring approximately 1.5" in length consisting of a swabable luer adaptor on one end and a tapered bore on the opposite end. The swabable female luer mates with a luer-type syringe tip and the 0 tapered bore mates (press fit) with the male end of a Toomey Syringe Adapter and allows for the transfer of material from a Toomey style syringe into a luer style syringe.

Toomey Syringe Adapter
The Toomey Syringe Adapter is a sterile, single use, male / female cylinder measuring approximately 1.5" in length and 0.75mm in diameter at the female end and 0.25" on the male end. The female end has a tapered bore of approximately 0.5" and is designed to mate (press fit) with a Toomey-style irrigation syringe. The male end of the Toomey Syringe Adapter is designed to mate (press fit) with the tapered end of the Luer-Lock Syringe Adaptor which allows for the transfer of material from a Toomey style syringe to a luer style syringe. The male end of the Toomey Syringe Adapter is also designed to fit into the Tissue Inlet Port of the PureGraft 250mL Bag which allows for the transfer of tissue from a Toomey style syringe into the PureGraft 250mL Bag.

Material Composition
The Cytori PureGraft 250/PURE System is fabricated from medical grade, DEHP free materials.

Sterility
The Cytori PureGraft 250/PURE System is sterilized with gamma irradiation.

In Vitro Testing
Mechanical testing of the Cytori PureGraft 250/PURE System demonstrates that the device is substantially equivalent to the predicate devices.

EQUIVALENCE TO MARKETED PRODUCT

The Cytori PureGraft 250/PURE System shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to premarket devices: the Cytori AFT System (K072587), the Shippert Medical Tissu-Trans (K050797), and the Lipose Fat Transfer System (K081848); Class II medical devices that were cleared for marketing in the United States under K072587, K050797, and K081848 respectively.

Indications for Use

The Cytori PureGraft 250/PURE System and the predicate devices are substantially equivalent with respect to their indications for use, as they are all indicated for the same surgical procedures of harvesting, filtering and transferring of autologous fat tissue for reinjecting back into the same patient.

Design and Materials

The design and materials of the Cytori PureGraft 250/PURE System and the predicate devices are substantially equivalent, as they are all single-use, polymer constructed, manually operated systems that receive adipose tissue, filter the adipose tissue, and temporarily hold the adipose tissue until it is removed or placed into a syringe that delivers / re-injects the adipose tissue back into the same patient during the same surgical procedure. The Cytori PureGraft 250/PURE System is substantially equivalent to the predicate devices as they all consist of a polymeric housing chamber with a filter unit within the chamber. These predicate devices also share design principles of accepting adipose tissue from the patient and subsequently transport the adipose tissue through a tube into a polymeric collection chamber/bag that contains a filtering mechanism of various pore sizes that restricts the movement of adipose tissue and only allows fluids and small debris to pass through the filter and become deposited into a waste container. The Cytori PureGraft 250/PURE System is also substantially equivalent to the predicate devices as they all have substantially equivalent tissue volume capacities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 6 2010

Cytori Therapeutics, Inc.
% Mr. Kenneth K. Kleinhenz
VP of Regulatory Affairs &
Quality Assurance
3020 Callan Road
San Diego, California 92121

Re: K092923
Trade/Device Name: Cytori PureGraft 250/PURE System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: January 4, 2010
Received: January 5, 2010

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):K092923

Device Name: Cytori PureGraft 250/PURE System

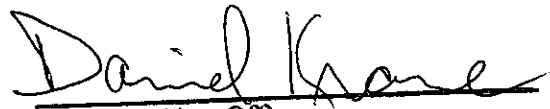
Indications For Use:

The Cytori PureGraft 250/PURE System is indicated for use in the harvesting filtering and transferring of autologous fat tissue for reinjecting back into the same patient for aesthetic body contouring.

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



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092923