ADMINISTRATIVE INFORMATION

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: Puregraft® 850/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 Puregraft® 850/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 Puregraft® 850/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. The Puregraft® 850/PURE System consists of collection bags, tubing and syringe adaptors that all have unique connectors and fittings to assure proper assembly. The Puregraft® 850/PURE System is composed of the following components:

Component	Description	Quantity
1	Puregraft® 850 Bag	1
2	Puregraft® 850 Drain Bag	1
3	Tissue Access Port Adapter (TAPA)	12
4	Luer Lock Syringe Adapter	2

In addition to the Puregraft® Assemblies described above, the Puregraft® 850/PURE System is used in combination with the following Class I hand-held manual instruments provided by Cytori Therapeutics:

Instruments Used in Conjunction with the Puregraft® 850/PURE System			
Instrument Name	**Configuration**	**Function**	**Quantity**
Easel	Anodized Aluminum Stand	Supports Puregraft® 850 Bag	1
Slider	Hand-held Anodized Slider Tool	Externally compresses Puregraft® 850 Bag to force liquid through filter and into Puregraft® Drain Bag.	1

Puregraft® 850 Bag

The Puregraft® 850 Bag is a sterile, single-use, 1275mL capacity mixing bag measuring approximately 12" x 9" and consists of 2 filters layered between a polyvinyl chloride (PVC) outer shell and 4 ports on the bottom of the bag. Each port is labeled and uniquely designed to assure the proper connection is made and to alleviate confusion. The "auxiliary" port contains a female bore connector, and the "drain" port contains a male bore connector fitting. The "inlet" port contains a female swabable luer fitting, and the "tissue" port contains a Toomey syringe adapter female fitting. The "tissue" port and the "inlet" port are designed as one-way valves to assure that the contents within the Puregraft® 850 Bag are not accidently spilled from the bag. The Puregraft® 850 Bag contains two (2) filters that are continuous within the bag. The first filter is an 800 micron filter mesh and the second filter is a 74 micron filter mesh. All materials are medical grade and DEHP free.

K111 3255
3 of 4

Puregraft®850 Drain Bag

The Puregraft® 850 Drain Bag is a sterile, single use, 5 liter bag measuring approximately 11" x 8" with a 0.125 inch drain tube measuring 48 inches 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® 850 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 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.

Tissue Access Port Adapter (TAPA)

The Tissue Access Port Adapter (TAPA) 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 Tissue Access Port Adapter is designed to mate (press fit) with the tapered end of the Luer-Lock Syringe Adapter 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® 850 Bag which allows for the transfer of tissue from a Toomey style syringe into the Puregraft® 850 Bag.

Material Composition

The Puregraft® 850/PURE System is fabricated from medical grade, DEHP free materials.

Sterility

The Puregraft® 850/PURE System is sterilized with gamma irradiation.

In Vitro Testing

Mechanical testing of the Puregraft® 850/PURE System demonstrates that the device is substantially equivalent to the predicate devices.

EQUIVALENCE TO MARKETED PRODUCT

The Puregraft® 850/PURE System shares indications and design principles with the following predicate device which has been determined by FDA to be substantially equivalent to a premarket device: the Cytori Puregraft® 250/PURE System (K092923); a Class II medical device that has been cleared for marketing in the United States under K092923.

Indications for Use

The Puregraft® 850/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 Puregraft® 850/PURE System and the predicate device are substantially equivalent, as they are both 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 Puregraft® 850/PURE System is substantially equivalent to the predicate device as they both consist of a polymeric housing chamber with a filter unit within the chamber. The predicate device also shares design principles of accepting adipose tissue from the patient and subsequently transport the adipose tissue through a port 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 Puregraft® 850/PURE System is also substantially equivalent to the predicate device as they both have substantially equivalent tissue volume capacities.

Nonclinical Summary

As a means to confirm the substantial equivalence between the Puregraft® 250/PURE System and the Puregraft® 850/PURE System, nonclinical testing was performed on the Puregraft® 850/PURE System and Puregraft® 250/PURE System predicate device that included biological performance verification and bench-top testing such as tensile strength, pressure, and drop testing. The nonclinical testing demonstrates that the Puregraft® 850/PURE System is substantially equivalent to the Puregraft® 250/PURE System predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR - 7 2012

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

Re: K113255
Trade/Device Name: Puregraft® 850/PURE System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: February 16, 2012
Received: February 17, 2012

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. 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,

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

Device Name: **Puregraft® 850/PURE System**

Indications for Use:

The Puregraft® 850/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 K113255