ADMINISTRATIVE INFORMATION

JAN 24 2014

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

DEVICE NAME

Classification Name:	Suction Lipoplasty System
Trade/Proprietary Name:	Puregraft® 50 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 50 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 50 System is a sterile, single use, closed system intended for the preparation and delivery of autologous fat grafts back to the same patient for aesthetic body contouring in cosmetic and reconstructive surgery applications. The dual filtration bag system connects to an off the shelf sterile luer lock syringe through a swabable luer activated valves interface. The attached slider is used to facilitate the movement of liquids through the filter mesh and out of the Puregraft bag through the drain stub as waste. The Puregraft 50 System is composed of the following components:

Description	Quantity
Outer Membrane	2
Filter 74 micron	1
Filter 800 micron	1
Tissue Port	1
Drain Port	1
Attached Slider	1

The Puregraft 50mL System is a sterile, single-use, 100mL capacity mixing bag measuring approximately 184 mm x 96 mm and consists of 2 filters layered between a polyvinyl chloride (PVC) outer shell and 2 ports on the bottom of the bag. Each port is labeled and designed to assure the proper connection is made with a luer fitting. The "tissue" port and the "drain" port contains a female swabable luer fitting designed to connect to a luer syringe. The "tissue" port and the "drain" port are designed as one-way valves to assure that the contents within the Puregraft 50mL Bag are not accidently spilled from the bag. The Puregraft 50mL Bag contains two (2) filters that are continuous within the bag. The first filter is a 800 micron filter mesh and the second filter is a 74 micron filter. The Puregraft 50 Bag has an attached plastic "slider" that is used to compress the Puregraft bag as a means to facilitate the movement of liquids through the filter mesh and out of the Puregraft bag to waste; through the "drain" port. All materials are medical grade and DEHP free.

Material Composition

The Puregraft 50 System is fabricated from medical grade polymers and are all DEHP free materials.

Sterility

The Puregraft 50 System is sterilized with gamma irradiation.

In Vitro Testing

Mechanical testing of the Puregraft 50 System demonstrates that the device is substantially equivalent to the predicate devices.

EQUIVALENCE TO MARKETED PRODUCT

The Puregraft 50 System shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to a premarket device: the Cytori Puregraft® 250/PURE System (K092923), and Puregraft 850/PURE System (K113255); both are a Class II medical device that have been cleared for marketing in the United States under K092923 and K113255 respectively.

Indications for Use

The Puregraft 50 System and the predicate devices are substantially equivalent as they share identical indications for use language and they are all indicated for the same surgical procedures of harvesting, filtering, and transferring autologous tissues for reinjecting back into the same patient for body contouring. The Puregraft 50 System's indications for use are identical to the cleared indications for use of the predicate devices. Specifically, the Cytori Puregraft 50 System is indicated for:

> The Cytori Puregraft 50 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.

Design and Materials

The design and materials of the Puregraft 50 System and the Puregraft 250/PURE System (K092923) and Puregraft 850/PURE System (K113255) 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 Puregraft 50 System is substantially equivalent to the predicate devices as they are all constructed of a polymeric flexible housing bag with a filter unit within the bag and ports to accept and remove the tissue with a syringe. 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.

Mechanical and Nonclinical Testing Summary

As a means to confirm the substantial equivalence between the Puregraft 50 System, the Puregraft 250/PURE System Puregraft 850/PURE System, nonclinical testing was performed on the Puregraft 50 System in addition to the 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 50 System is substantially equivalent to the Puregraft 250/PURE System and Puregraft 850/PURE System predicate devices.

Substantially Equivalent Testing Summary

	Puregraft 50 (Subject Device)	Puregraft 250 (K092923)	Correlation
Lipolysis (fold change)	PASS	PASS	Substantially Equivalent
Wetness (% of control)	PASS	PASS	Substantially Equivalent
Lipid Content (% of control)	PASS	PASS	Substantially Equivalent
RBC (% of control)	PASS	PASS	Substantially Equivalent
WBC (% of control)	PASS	PASS	Substantially Equivalent
Integrity Testing	PASS	PASS	Substantially Equivalent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Cytori Therapeutics Incorporated
Mr. Kenneth K. Kleinhenz
Vice President, Global Regulatory Affairs
3020 Callan Road
San Diego, California 92121

January 24, 2014

Re: K132815
Trade/Device Name: Puregraft 50 System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: December 24, 2013
Received: December 26, 2013

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 contact 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
For Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132815

Device Name
Puregraft 50 System

Indications for Use *(Describe)*
The Puregraft 50 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S