



CYTORI THERAPEUTICS INC.
Attention: Kenneth Kleinhenz, Sr.
3020 Callan Rd,
San Diego, CA 92121-1109

February 9, 2023

Re: BK220684 (Formally K072587)
Trade/Device Name: CYTORI AFT SYSTEM
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL, QUB

Dear Mr. Kleinhenz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 10, 2007. Specifically, FDA is updating this SE Letter because FDA has assigned your submission a new submission tracking number and created a new product code to better categorize your device technology.

Please update the registration and listing of the device within the FURLS Device Registration and Listing Module according to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm>.

For more information, please refer to the Federal Register Notice *Consolidation of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care To Produce a Therapeutic Article* (86 FR 50887, available at <https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based>).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact the Regulatory Project Manager, Candace Jarvis at (240) 402-8315 or by email at Candace.Jarvis@fda.hhs.gov.

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

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: Suction Lipoplasty System
Trade/Proprietary Name: Cytori AFT System

DEC 10 2007

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.

INTENDED USE

The Cytori AFT System is used in the aspiration, harvesting, filtering and transferring of autologous tissue.

The Cytori AFT System is intended for use in the following surgical specialties when the aspiration of soft tissue is desired:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery

The Cytori AFT System is indicated for use when the fragmentation, emulsification, and aspiration of subcutaneous fatty tissues for aesthetic body contouring is desired.

DEVICE DESCRIPTION

Design Characteristics

The Cytori AFT System is provided in two packaged assemblies: 1). Cytori AFT Tissue Collection Canister and 2). Cytori AFT Delivery Syringe. The Cytori AFT Tissue Collection Canister is a single-use disposable device designed to utilize house vacuum to create suction within the hollow liposuction cannula and remove subcutaneous fatty tissue from the patient and transport the adipose tissue into the collection canister. The Cytori AFT Delivery Syringe is a, sterile, single-use 60cc piston syringe.

AFT Tissue Collection Canister

The Cytori AFT Tissue Collection Canister is a sterile, single-use, manual device consisting of a cannula, connection tubing and a tissue collection container that relies on house vacuum for its energy supply. The cannula handle is attached to the tissue collection container via connection tubing. The cannula is a hollow tube with a single opening near the tip to communicate house vacuum to the tissues and subsequently aspirate, harvest and filter subcutaneous fatty tissues from the patient into the tissue collection container. The cannula tip is fabricated from medical grade stainless steel and the handle is fabricated from medical grade polypropylene. The connection tubing is fabricated from medical grade polyvinyl chloride (PVC) that is DEHP free. The Collection Canister is fabricated from medical grade polycarbonate to assure robustness in the operating room environment. The tissue collection container contains various capped/sealed luer ports and a 265 micron filter to entrap the tissue while allowing liquid to pass through to a hospital-provided collection trap.

The stainless steel cannula that contacts the patient is provided in various sizes ranging from 15 – 36 cm in length and 3.0 – 4.6 mm in diameter with a single opening near the tip of the cannula. The tip region of the cannula may have a single or multiple openings that range in size from 4 to 12 mm in length distributed uniformly or randomly throughout the end of the cannula. The handle of the device is provided with a diameter of 20 mm and may be provided in diameters ranging from 20 to 60 mm. The connecting tubing is provided with an inner diameter of 9.6 mm (3/8”), an outer diameter of 14.3 mm (9/16”), and a wall thickness of 2.2 mm. The tubing that connects the cannula handle to the tissue collection canister is provided in a length of 4 feet and may be provided in lengths ranging from 1 – 8 feet. The bottom of the tissue collection canister is also provided with the same 3/8” inner diameter connection tubing of various lengths. The proximal end of the exiting connection tubing may be provided with a barbed tubing connector to assist in the attachment of like-sized tubing for purposes of connecting the Cytori AFT System to house vacuum and/or assorted waste traps. Connection tubing leading to and from the tissue collection container is provided with a stepped clamp to facilitate manual control of the vacuum supplied to the cannula. The stepped clamps also allow the operator to seal the connection tubing on both sides of the Collection Canister and prevent spillage of the collected fluids/tissues, thereby facilitating safe transport and disposal of the waste materials.

AFT Delivery Syringe

The Cytori AFT Delivery Syringe is a polymeric 60cc volume luer-lock style sterile, single-use syringe consisting of a polypropylene barrel with printed graduations, a polypropylene plunger, and a polyisoprene latex free rubber stopper at the end of the plunger.

Material Composition

The components of the Cytori AFT System that have direct patient contact are fabricated from surgical stainless steel.

Sterility

The Cytori AFT System is sterilized by ethylene oxide (EtO) gas.

In Vitro Testing

Mechanical testing of the Cytori AFT System demonstrates that the device is substantially equivalent to the predicate devices.

EQUIVALENCE TO MARKETED PRODUCT

The Cytori AFT System shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to premarket devices: Shippert Medical Tissu-Trans (K050797), MacroPore Puricel Lipoplasty System (K042261), Exel International Disposable Syringe (K861153) and Genesis Biosystems Lipivage (510(k) number unknown); Class I and II medical devices that were cleared for marketing in the United States under K050797, K042261, and K861153, respectively.

Indications for Use

The Cytori AFT 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 aspirating, harvesting, filtering, and transferring autologous tissues.

Design and Materials

The design and materials of the Cytori AFT System and the predicate devices [Shippert Medical Tissu-Trans (K050797), MacroPore Puricel Lipoplasty System (K042261), Exel International Disposable Syringe (K861153) and Genesis Biosystems Lipivage (510(k) number unknown)] are substantially equivalent, as they are all single-use, polymer constructed, manually operated systems that utilize manual or external sources of vacuum to withdraw, hold, and/or inject fluids/tissues into the body. The Cytori AFT System is substantially equivalent to the Tissu-Trans (K050797), Puricel Lipoplasty System (K042261), and the Lipivage predicate devices, as they all consist of a polycarbonate tissue collection canister with flexible tubing attached to a stainless steel cannula that contacts the patient. The Cytori AFT System is substantially equivalent to the Tissu-Trans (K050797), Puricel Lipoplasty System (K042261), and the Lipivage predicate devices, as they all share design principles of utilizing house-vacuum to aspirate adipose tissue from the patient and subsequently transport the adipose tissue through a tube into a cylindrical collection chamber that contains a filtering mechanism of pores to allow fluids to pass, but retains the adipose tissue within the chamber. The Cytori AFT System is substantially equivalent to the Tissu-Trans (K050797), Puricel Lipoplasty System (K042261), and the Lipivage predicate devices, as they all consist of a polymeric housing chamber with a filter unit within the chamber. The Cytori AFT System is substantially equivalent to the Tissu-Trans (K050797), Puricel Lipoplasty System (K042261), and the Lipivage predicate devices, as they all have connection ports on the superior ends of the housing chamber for the attachment of suction tubing/stainless steel cannulas that contact the patient and connection ports on the inferior end of the housing chamber to connect to vacuum tubing that draws house vacuum and carries waste to the waste trap. The Cytori AFT System is substantially equivalent to the Tissu-Trans (K050797) and the Lipivage predicate devices, as they are all equipped with a separately packaged plunger device to deliver the tissue back to the same patient.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 2007

Cytori Therapeutics, Inc.
% Mr. Kenneth K. Kleinhenz
Sr. Director of Regulatory Affairs
3020 Callan Road
San Diego, California 92121

Re: K072587
Trade/Device Name: Cytori AFT System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: September 12, 2007
Received: September 14, 2007

Dear Mr. Keinhenz:

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.

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number: K072587

Device Name: Cytori AFT System

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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)


(Division Sign-Off)

Concurrence of CDRH Office of Device Evaluation (ODE)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K072587