Shippert Medical Technologies

The Denver Splint Company

6248 S. Troy Circle, Unit A
Centennial, CO 80111
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Section 5: 510(k) SUMMARY

Name: Shippert Medical Technologies
6248 South Troy Circle, Unit A
Centennial, Colorado 80111
Tele: 303.754.0044
Fax: 303.754.0318

Date: December 4, 2009

Official Contact: Sarah Lake Shippert Telephone (303) 888.4965
email: sarah@shippertmedical.com
Submitted by: Sarah Lake Shippert

FDA ESTABLISHMENT REGISTRATION NUMBER: 1718903

DEVICE NAME: Tissu Trans Filtron

Tradename:	Tissu Trans Filtron
Common Name:	Suction Lipoplasty System
Classification name:	Suction Lipoplasty System
Product Code:	MUU
Regulation Number:	21 CFR 878.5040
Class II	Sterile

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.

K092482/5

INDICATIONS FOR USE:

The Tissu Trans Filtron is intended to be used with house vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be reinjected via a cleared injection apparatus.

INTENDED USE:

The Tissu Trans Filtron is intended to be used with house vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be reinjected via a cleared injection apparatus.

Tissu Trans Filtron is used in the aspiration, harvesting, filtering and transferring of autologous tissue.

Tissu Trans Filtron is intended for use in the following surgical specialties when the aspiration of soft tissue is desired:

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

DESIGN CHARACTERISTICS:

The Tissu Trans Filtron is provided in a sterile, two piece packaged assembly: The Tissu Trans Filtron. The Tissu Trans Filtron is a single-use, sterile, disposable device designed to utilize an FDA cleared house vacuum to create suction within the physician supplied hollow liposuction cannula and remove subcutaneous fatty tissue from the patient and transport the autologous tissue into the collection canister.

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DEVICE COMPONENTS:
The Tissu Trans Filtron is a sterile, single-use, manual device consisting of a medical grade polycarbonate canister, a medical grade polypropylene lid with various ports, medical grade silicone connection tubings for aspiration of waste, harvesting of tissue and transferring of filtered autologous tissue. A polypropylene clamp is included for clamping off the tubing as needed. A medical grade polyester mesh filter lining is contained within the canister.

Material Composition:
The components of the Tissu Trans Filtron do not have direct patient contact. The necessary FDA cleared liposuction cannula (direct patient contact) is supplied by the physican.

All components of the Tissu Trans Filtron have been tested and have passed the ISO 10993 testing regimen for External Communication Devices, Tissue contact, of less than 24 hours. All necessary biocompatibility testing was performed on the sterile, finished device.

STERILITY:

The Tissu Trans Filtron is sterilized by Gamma Radiation.

IN VITRO TESTING:

Mechanical testing of the Tissu Trans Filtron demonstrates that the device is substantially equivalent to the predicate device. Device Performance was satisfied by clinical testing performed by Ronald Shippert, M.D. All testing proved to be safe and effective. The device performed as desired and was as safe and as effective as the predicate devices.

EQUIVALENCE TO MARKETED DEVICES:

The Tissu Trans Filtron share indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to premarket devices: Cytori AFT System k072587, Tissu Trans k050797, and Genesis Biosystems Lipivage (510(k) number unknown); Class I and Class II medical devices that were cleared for marketing in the United States.

Design and Materials:
The design and materials of the Tissu Trans Filtron and the predicate devices, (Cytori AFT System 072587, Shippert Medical Tissu Trans k 050797, Genesis Biosystems Lipivage k# unknown, are substantially equivalent, as they are all single-use, polymer constructed, manually operated systems that utilize manual

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or external sources of vacuum to withdraw, hold, and/or inject fluids/tissues into the body. The Tissu Trans Filtron is substantially equivalent to the Cytori AFT System k072587, The Shippert Medical Tissu Trans k050797 and the Lipivage k# unknown, predicate devices as they all consist of a polycarbonate tissue collection canister and they share design principles of utilizing an FDA cleared 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 filter chamber. The Tissu Trans Filtron is substantially equivalent to the Cytori AFT System k072587, Shippert Medical's Tissu Trans 050797 and Genesis Biosystems Lipivage k# unknown, 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.

Substantial Equivalence: Shippert Medical Technologies claim substantial equivalence to the predicate devices.

Predicate Device # 1:

Cytori AFT System , k 072587
- Classification Name: Suction Lipoplasty System
- Class 2 Device,
- Product Code MUU
- Regulation Number 878.5040
- General Hospital Classification Advisory Committee
- General & Plastic Surgery Review Advisory Committee

and

Predicate Device # 2:

Shippert Medical's " Tissu Trans", k050797
- Classification name: Syringe, Irrigating (Non Dental)
- Class 1 Device, Sterile
- Product Code: KYZ
- Regulation #: 880.6960
- General Hospital Classification Advisory Committee
- General & Plastic Surgery Review Advisory Committee

and

Predicate Device # 3

Genesis Biosystems Lipivage k# unknown
- Classification name:
- Class 2 Device, Sterile
- Product Code: MUU
- Regulation #: 878.5040
- General Hospital Classification Advisory Committee
- General & Plastic Surgery Review Advisory Committee

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Summary: The Shippert Medical Tissu Trans Filtron device described in this submission is substantially equivalent to the predicate devices and is safe and effective. The proposed device and predicate devices have identical "Intended Use" and similar Indications For Use" and also share similar design and technological principles. The device design and materials used are similar to those of the Predicate Devices, Cytori AFT System k 072587, Shippert Medical Tissu Trans, K05079 and Genesis Biosystems Lipivage k# unknown.

As stated in CFR 878.5040, (product code MUU),

a., "Identification. A suction lipoplasty system is a device intended for aesthetic body contouring. The device consists of a powered suction pump (containing a microbial filter on the exhaust and a microbial in-line filter in the connection tubing between the collection bottle and the safety trap), collection bottle, cannula, and connecting tube. The microbial filters, tubing, collection bottle, and cannula must be capable of being changed between patients. The powered suction pump has a motor with a minimum of 1/3 horsepower, a variable vacuum range from 0 – 29.9 inches of mercury, vacuum control valves to regulate the vacuum with accompanying vacuum gauges, a single or double rotary vane (with or without oil), a single or double diaphragm, a single or double piston, and a safety trap.

Given the "Intended Use", "Indications For Use", device technology, materials and basic design structure of Product Code MUU & KYZ; Shippert Medical Technologies claim Substantial Equivalence to the above listed devices.

EXHIBIT D-1: LABEL

Tissu Trans Filtron™

Indications For Use:

The Tissu Trans Filtron is intended to be used with house vacuum and/or cleared pumps, tubing and cannulas, for the collection of aspirated fat, for aesthetic body contouring. If the fat is untreated, it may be reinjected via a cleared injection apparatus.

Tissu Trans Filtron is used in the aspiration, harvesting, filtering and transferring of autologous tissue. Tissu Trans Filtron is intended for use in the following surgical specialties when the aspiration of soft tissue is desired: Plastic and Reconstructive Surgery, Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery.

Product Code: 3-TT-Filtron 2000-500

Contents: 1 Tissu Trans Filtron Unit with 6' Harvest Tubing
1 7" Transfer Tubing with Luer Lock

Warnings Section

1. This device will not, in and of itself, produce significant weight reduction.
2. This device should be used with extreme caution in patients with chronic medical conditions, such as diabetes; heart, lung, or circulatory system disease; or obesity.
3. The volume of blood loss and endogenous body fluid loss may adversely affect intra and/or postoperative hemodynamic stability and patient safety. The capability of providing adequate, timely replacement is essential for patient safety.

Precautions Section

1. This device is designed to contour the body by removing localized deposits of excess fat through small incisions.
2. Use of this device is limited to those physicians who, by means of formal professional training or sanctioned continuing medical education (including supervised operative experience), have attained proficiency in suction lipoplasty.
3. Results of this procedure will vary depending upon patient age, surgical site, and experience of the physician.
4. Results of this procedure may or may not be permanent.
5. The amount of fat removed should be limited to that necessary to achieve a desired cosmetic effect.
6. All reusable components of the device must be sterilized and all disposable components replaced before using the device system on another patient.

WARNING(S):
DO NOT REUSE OR RESTERILIZE.
INTENDED FOR SINGLE PATIENT USE.

USE ONLY WITH A MEDICAL GRADE VACUUM OR ASPIRATOR APPARATUS

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Consult Instructions for Use

Rx Only

Pyrogen Free.

Caution: Federal law restricts this device to sale by or on the order of a physician.

CE 0470

CEpartners4U BV
Esdoornlaan 13
3951DB Maarn
The Netherlands

Contents of unopened, undamaged package
Are STERILE AND NON-PYROGENIC.

Shippert Medical Technologies
Centennial, CO USA
to re-order:
1-800-888-8663 phone
1-800-284-0864 fax
www.shippertmedical.com

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December 4, 2009

Mr. George Ngatha
FDA CDRH
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear George,
Enclosed please find the requested documents for 510k 092482:

Revised Indications For Use
Revised Summary.

Hard copies will follow by mail along with revised labeling.

Thank you,

Sarah Lake Shippert

FDA FAX# 301.847.8183

8 pages

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

Shippert Medical Technologies Corp.
% Ms. Sarah Shippert
Head, Regulatory Affairs
6428 South Troy Circle, Unit A
Centennial, Colorado 80111

DEC - 4 2009

Re: K092482
Trade/Device Name: Tissu Trans Filtron
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: November 17, 2009
Received: November 27, 2009

Dear Ms. Shippert:

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/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,

for

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

Enclosure

K092482 1/1

Indications For Use

510k Number if known: k092482

Device Name: **Tissu Trans Filtron**

Indications for Use:

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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

Concurrence of CDRH Office of Device Evaluation (ODE)

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

510(k) Number K092482