SHIPPERT MEDICAL TECHNOLOGIES CORP. **February 9, 2023**
Attention: Becky Aldhizer
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Email Address: (b) (6) @steris.com

Re: BK220692 (Formally K102117)
Trade/Device Name: TISSU TRANS FILTRON SYRINGE FILL
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Ms. Aldhizer:

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 August 6, 2010. 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, Hosna Keyvan by email at hosna.keyvan@fda.hhs.gov.

Sincerely,

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

Enclosure

Section 19: 510(k) SUMMARY k# 102117

As required by 807.97

SPECIAL 510(k) APPLICATION

Prepared By:
Shippert Medical Technologies
6248 South Troy Circle, Unit A
Centennial, Colorado 80111
Tele: 303.754.0044
Fax: 303.754.0318
Contact: Sarah Lake Shippert Telephone (303) 888.4965
Email: sarah@shippertmedical.com

Date: July 20, 2010

AUG - 6 2010

Submitted by: Sarah Lake Shippert

FDA Establishment # 1718903

Proposed Device:

Tradename:	Tissu Trans Filtron Syringe Fill
Model/Product Number:	3-TT-Filtron Syringe Fill
Common Name:	Suction Lipoplasty System
Classification name:	Suction Lipoplasty System
Product Code:	MUU
Regulation Number:	21 CFR 878.5040
Device: Class II,	Sterile

Submission Purpose: Modification to:
Shippert Medical's Tissu Trans Filtron, k092482

Predicate Device: Shippert Medical's Tissu Trans Filtron, k092482

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

Tissu Trans Filtron Syringe Fill 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: Shippert Medical's Tissu Trans Filtron Syringe Fill 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 Syringe Fill is used in the aspiration, harvesting, filtering and transferring of autologous tissue.

Tissue 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

The Indications For Use and the Intended Use are identical to the Predicate Device, Tissu Trans Filtron k092482.

Design Characteristics:

Tissu Trans Filtron Syringe Fill is an optional accessory to Shippert Medical's Tissu Trans Filtron, k092482. Shippert Medical's Tissu Trans Filtron Syringe Fill is a sterile, single use, disposable device used in the aspiration, harvest, filtering and transferring of autologous tissue. Used by physicians in the harvesting of body tissues, this device is a single use, disposable sterile canister with six enclosed 60cc syringes used for collecting the harvested tissue after harvesting/aspiration..The harvested tissue is stored in the Syringe Fill syringes and is intended for immediate reinjection of the harvested tissue back into the donor patient.

Device Components:

The Tissu Trans Filtron Syringe Fill connects to the inverted Tissu Trans Filtron, k092482, with an accessory silicone tubing piece which is included in the Tissu Trans Filtron Syringe Fill packaging. This tubing is connected onto the the Tissu Trans Filtron Syringe Fill's lid at the appropriate in-take port. This same transfer tubing is then connected onto the inverted Tissu Trans Filtron at its out-take port. The vacuum tubing from the Tissu Trans Filtron is repositioned from the Tissu Trans Filtron's vacuum port to the Tissue Trans Filtron Syringe Fill's vacuum port. When the vacuum pump is turned

on the Tissu Trans Filtron Syringe Fill's six syringes begin to fill up as the physician releases the pinch clamp. As one syringe is filled, the tissue continues to fill the subsequent syringes. A pinch clamp is used to close off the silicone transfer tubing after the final sixth syringe is filled and the vacuum pump is turned off. The physician or OR staff will remove the filled syringes and place a physician supplied FDA approved re-injection cannula onto the syringe's luer lock. The syringe's plunger will be inserted at the large open end of the syringe and re-injection of the autologous tissue can proceed.

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

All components of the Tissu Trans Filtron Syringe Fill 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 Syringe Fill is sterilized by Gamma Radiation.

In Vitro Testing:

Clinical testing was conducted by Ronald D. Shippert, M.D. to validate and verify that the proposed device met all design specifications. Validation tests were conducted to validate the design control activity. Performance of the Tissu Trans Filtron Syringe Fill satisfies all design specifications. Mechanical testing of the Tissu Trans Filtron Syringe Fill 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 device.

Equivalence To Marketed Device: Shippert Medical's Tissu Trans Filtron Syringe Fill is substantially equivalent to the Tissu Trans Filtron device under K092482. This new device is an optional accessory to the Shippert Medical Technologies Tissu Trans Filtron device.

Shippert Medical Technologies Tissu Trans Filtron k092482
Classification Name: Suction Lipoplasty System
Class 2 Device,
Product Code MUU
Regulation Number 878.5040,
General Hospital

As stated in 21 CFR 878.5040 , (product code MUU), 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 2. They have been assigned Product Code MUU.

As 21 CFR 878.5040 states the existence of a "collection bottle and detachable tube" in the description of Product Code MUU, Shippert Medical is now modifying the original Tissu Trans Filtron, k092482 to offer an additional canister (collection bottle) and a detachable tube as an optional accessory.

Technological Characteristics: Shippert Tissu Trans Filtron Syringe Fill is used in conjunction with a hospital or facility supplied vacuum-powered body fluid suction apparatus which is capable of a low pressure setting of 15" of mercury. The Tissu Trans Filtron Syringe Fill is an optional accessory to the Tissu Trans Filtron, k 092482. The technological characteristics of the Tissu Trans Filtron Syringe Fill follow those of its predicate, Tissu Trans Filtron, k092482.

This device is sterilized by Gamma Radiaiton, same as the predicate device, k092482.

Summary: The Shippert Medical Tissu Trans Filtron Syringe Fill device described in this submission is a modification to the previously 510(k) cleared device, Tissu Trans Filtron k092482. This modification is substantially equivalent to the Tissu Trans Filtron k092482 predicate device and is safe and effective.

The modified device has the same classification, the same indications, the same intended use, the same fundamental technology, the same design structure as described in 878.5040, the same sterility protocol and the same safety and effectiveness performance as the predicate device.

Given the "Intended Use, Indications For Use, device technology, materials and basic design structure of Product Code MUU, Shippert Medical Technologies claim Substantial Equivalence to Tissu Trans Filtron, k092482.

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

Shippert Medical Technologies
% Ms. Sarah Lake Shippert
6248 South Troy Circle, Unit A
Centennial, Colorado 80111

AUG - 6 2010

Re: K102117
Trade/Device Name: Tissu Trans Filtron Syringe Fill
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: MUU
Dated: July 20, 2010
Received: July 28, 2010

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. 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,

for

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

Enclosure

K102117

Indications for Use

510(k) Number (if known): k102117

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Device Name: Tissu Trans Filtron Syringe Fill

Tissu Trans Filtron Syringe Fill 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.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

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

510(k) Number K102117