

JUL 13 2005

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## Section 3: 510(k) SUMMARY

**Name:** Shippert Medical Technologies  
6248 South Troy Circle, Unit A  
Centennial, Colorado 80111  
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Contact: Sarah Lake  
Email: [sarah@shippertmedical.com](mailto:sarah@shippertmedical.com)

Date: March 16, 2005

**Tradename:** Tissue-Trans™  
**Common Name:** Syringe, irrigating  
**Classification name:** Syringe, irrigating (Non-Dental)  
**Product Code:** KYZ  
**Regulation Number:** 21 CFR 880.6960  
**Class I** Sterile

**Substantial Equivalence:** Shippert Medical is requesting a claim of substantial equivalence to two devices as listed under Product Code KYZ. We can only find one of these devices 510(k) number. See below.

Shippert Medical is requesting a claim of Substantial Equivalence to the device **Johnson & Johnson Syringe, (k)884749** Classification Name: Syringe, Irrigating (Non-Dental), Class I Device, Product Code KYZ, Regulation Number 880.6960, General Hospital. See Section 7 for Substantial Equivalence data, Exhibit E.

Shippert Medical is requesting a claim of substantial equivalence to the product **"LipiVage" manufactured and marketed by Genesis Biosystems.** "LipiVage" is a sterile, disposable syringe FDA listed device by Genesis Biosystems under Product Code KYZ. Classification name: Syringe, Irrigating (Non-Dental), Class I Device, Product Code KYZ, Regulation Number 880.6960, General Hospital. I have been unable to locate their 510(k) number for LipiVage. See Section 7 for Substantial Equivalence data, Exhibit F.

**Description of the Device:** Tissue-Trans™ is a sterile, single use, disposable syringe device used in the harvesting, filtering and transferring of autologous fat. Used by physicians in lipo-filling procedures, Tissue Trans™ simplifies and reduces the steps needed in the collection and transfer of the autologous fat. In so doing, the harvested fat is less traumatized and risk of contamination is lowered because the fat never leaves the harvesting syringe until re-injection.

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**Intended Use:** Tissu-Trans™ is intended to be used when harvesting, filtering and transferring of autologous fat is desired.

**Technological Characteristics:** Tissu-Trans™ is a piston syringe device comprised of a small 10cc syringe with Luer Lock tip that has small holes drilled into its barrel. This small 10cc syringe is placed inside a larger 60cc barrel type tube, which is attached to a medical grade tubing and aspiration machine. As the autologous fat is collected into the 10cc syringe, the waste products are strained through the holes in the 10cc syringe into the large 60cc barrel tube and suctioned into a waste container. The small syringe is removed from the large 60cc tube, a sleeve is attached to the small 10cc syringe around the barrel and the autologous fat is re-injected into the patient at desired locations.

Previous procedure technology demanded the aspiration, washing, centrifuging and re-injection of the then over-handled fat cells. Tissu-Trans™, like LipiVage, decreases the number of steps a physician must take to process the fat for re-injection. The fat remains in a sterile field at all times with Tissu-Trans™, thus reducing the risk of infection. The fat cells also are less traumatized due to the low vacuum levels, no centrifuging, less time outside of the body, and the fewer numbers of harvesting, washing, filtering and transfer steps.

**Summary:** The Tissu-Trans™ device described in this submission is substantially equivalent to the predicate devices, and is safe and effective.

The device design and materials used, are similar to those of the Predicate Device Johnson & Johnson Syringe k884749 and LipiVage, k# unknown, and also to most of the piston syringes in the Product Code KYZ.

As stated in CFR 880.6960, (product code KYZ) "An irrigating syringe is a device intended for medical purposes that consists of a bulb or piston syringe with an integral or a detachable tube. The device is used to irrigate, withdraw fluid from, or instill fluid into, a body cavity or wound."

Given the "Intended Use" and basic design structure of Product Code KYZ, Shippert Medical Technologies claims Substantial Equivalence to the above listed devices. Even given the Class I Exempt Device Status of Product Code KYZ, due to our product's sterile state, we are submitting a 510(k) Premarket Submission.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 13 2005

Ms. Sarah M. Lake  
Regulatory Affairs  
Shippert Medical Technologies  
6248 S. Troy Circle, Unit A  
Centennial, Colorado 80111

Re: K050797  
Trade/Device Name: Tissu-Trans™  
Regulation Number: 21 CFR 880.6960  
Regulation Name: Irrigating Syringe  
Regulatory Class: I  
Product Code: KYZ  
Dated: June 15, 2005  
Received: June 17, 2005

Dear Ms. Lake:

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.

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Miriam C. Provost, Ph.D.

Acting Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

K050797

**Section 2: STATEMENT OF INDICATIONS FOR USE**

510k Number if known: K050797

Device Name: Tissu-Trans™

Indications for Use:

Tissu-Trans™ is a piston syringe used in the aspiration harvesting, filtering and transferring of autologous tissue.



(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K050797

