K 101561

510(k) Summary

AUG 2 7 2010

510(k) Submitter/ Owner	American Optisurgical Inc. 25501 Arctic Ocean Lake Forest, CA 92630 Voice: (949) 580-1266 Fax: (949) 580-1270
Contact person	David Salzberg Director of Regulatory Affairs American Optisurgical, Inc. Email: regulatory@optisurgical.com
Date prepared	06/02/10
Trade name	TX1 Tissue Removal System
Common name	Ultrasonic Surgical Aspirator
Classification	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code LFL)
Predicate device	K021989, Selector Integra Ultrasonic Surgical Aspirator
Device description	The TX1 Tissue Removal System is an ultrasonic surgical aspirator that emulsifies and removes soft tissue. The system consists of a console, ultrasonic handpiece, tube set, and foot pedal. The system has been designed to work with commercially available accessories and consumables including cautery pencils and forceps, ultrasonic handpiece tips, and silicone sleeves. The console provides control over the four modes of operation including irrigation, aspiration, cutting, and coagulation. It has a large, color LCD and employs a touch-screen for selection of required settings. The console also provides audible tones for confirmation of selections. The console also houses the irrigation and aspiration pumps, thereby eliminating the need for a dedicated service cart or suction/waste source within the operating room. Two USB ports are available for loading software upgrades. An Ethernet port is also available for future system expandability.

The ultrasonic handpiece connects to the console for power, and to the tube set for both delivering irrigation fluid directly to the surgical site and for removing emulsified tissue. The handpiece is constructed from both 316L stainless steel and TiAl6V4 Titanium Alloy components, and can be sterilized by steam and reused multiple times.

The tube set employs an external tubing cartridge design that can be easily installed or removed in a single step. The tubing is made of biomedical grade silicone. The tube set can be sterilized by steam and reused multiple times.

Irrigation fluid is delivered under pressure to ensure adequate cooling of the ultrasonic tip, as well as adequate flushing of the surgical site, by operation of an air pump residing in the console. The regulated output of the air pump pressurizes a cuff that is fitted around the irrigating fluid bag, thus providing irrigation at a fixed pressure regardless of the height of the fluid bag.

The foot pedal is used to control each of the four functions of the system. Simple in design, it offers on/off functionality and is rated IPX5 for protection against liquids.

NOTE: The device is essentially the same device cleared to market under 510(k) K080803, with changes made to the frequency range, irrigation system, foot pedal, software, labeling, and console color.

Intended use

The TX1 Tissue Removal System is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

Technological characteristics

The TX1 Tissue Removal System has similar technological characteristics as the predicate device cleared under 510(k) K021989. A summary is as follows:

Table II – Summary of Device Characteristics

Device Characteristics	Subject Device TX1 Tissue Removal System	Predicate Device Selector® Integra Ultrasonic Surgical Aspirator
Indications for use	The TX1 is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue are desirable.	The Selector® is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue are desirable.
Display	Articulating, LCD Touch Screen	7 segment, manual pushbutton
Power source	100-240V 50/60Hz	100-240V 50/60Hz
Method of tissue emulsification	Ultrasonic energy	Ultrasonic energy
Frequency	28 kHz	24 kHz and 35 kHz
Tip Amplitude	Max 255µm	Max 24 kHz: 305µm Max 35 kHz: 215µm
Method of aspiration (vacuum)	Peristaltic pump	Venturi pump
Vacuum level	100, 300, or 500 mmHg	0 to 600 mmHg
Method of irrigation	Constant Pressure	Constant flow
Irrigation flow	10, 20, or 30 cc/min	0 to 50 cc/min
Material in contact with tissue	TiAl6V4 Titanium Alloy	TiAl6V4 Titanium Alloy
Electrical safety standards met	60601-1 60601-1-2 60601-2-2	60601-1 60601-1-2 CSA 22.2 #601-1

Conclusion

Independent, 3rd party electrical safety testing, adherence to U.S. FDA design control guidance, as well as thorough in-house, non-clinical (bench) testing and software validation provide reasonable assurance that the TX1 Tissue Removal System is safe and effective, and is, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.

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

American Optisurgical, Inc.
% Mr. David Salzberg
Director of Regulatory Affairs
25501 Arctic Ocean
Lake Forest, California 92630

AUG 27 2010

Re: K101561
Trade/Device Name: TX1 Tissue Removal System
Regulatory Class: Unclassified
Product Code: LFL, GEI
Dated: June 02, 2010
Received: June 04, 2010

Dear Mr. Salzberg:

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.

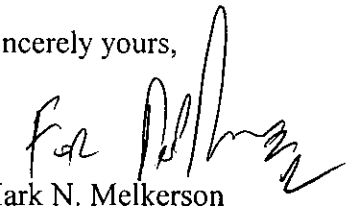
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

Indications for Use Statement

510(k) Number (if known): K101561

Device Name: TX1 Tissue Removal System

Indications for Use: The TX1 Tissue Removal System is indicated for use in surgical procedures where fragmentation, emulsification, and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.

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

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Surgical, Orthopedic,
and Restorative Devices

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