

K 982841

SEP 4 1998

510(k) SUMMARY - Alliger Ultrasonic Surgical System Model AUSS-4

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

1. Submitter's Identification

Name: MISONIX INCORPORATED
Address: 1938 New Highway, Farmingdale, NY 11735
Telephone Number: 516-694-9555
Contact Person: Ronald Manna
Date Prepared: 6/16/98

2. Name of Device

Proprietary Name: Alliger Ultrasonic Surgical System Model AUSS-4
Common/Usual Name: Ultrasonic Surgical System
Ultrasonic Surgical Aspirator
Classification Name: Instrument, Ultrasonic Surgical

3. Predicate Device Information

Predicate Device: ValleyLab CUSA® Model 200H Ultrasonic Surgical Aspirator
Spemby Selector® Ultrasonic Surgical Aspirator

4. Device Description:

The Alliger Ultrasonic Surgical System is comprised of a generator which feeds a 40 kHz electrical signal to piezoelectric crystals mounted in a hand-held Handpiece; the crystals then vibrate at the same frequency. The vibration is amplified by a titanium Tip attached to the Handpiece. Fragmentation of unwanted tissue occurs at the end of the Tip. An Irrigation/Aspiration unit is provided to introduce irrigation solution and remove fragmented material and waste liquids.

5. Intended Use:

The Alliger Ultrasonic Surgical System is indicated for use in the fragmentation and aspiration of soft tissue in the following surgical specialties:

Neurosurgery
Gastrointestinal and Affiliated Organ Surgery
Urological Surgery
Plastic and Reconstructive Surgery
General Surgery
Orthopedic Surgery
Gynecology

External genitalia

- condyloma
- benign tumors (lipomas, fibromas and leiomyomas)

- malignant primary and metastatic tumors of all types and the following cystic lesions: Bartholin's cysts, vestibular adenitis, inclusion cysts and sebaceous cysts.

Abdominal area

- any abnormal growth, cystic or solid, benign or malignant, involving the ovary, fallopian tube, uterus or the supporting structures of the uterus.

Thoracic Surgery

- limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies, and metastatectomies

6. Comparison to Predicate Device:

The Alliger Ultrasonic Surgical System is similar in design, material and operating parameters to the CUSA 200H® Ultrasonic Surgical Aspirator. Although the CUSA 200H® has a magneto-strictive transducer and the Alliger Ultrasonic Surgical System has a piezoelectric transducer, the Spemby Selector®, which also contains a piezoelectric transducer, has been previously determined by FDA to be substantially equivalent to the CUSA 200H®.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following engineering tests were performed to determine that operating characteristics are substantially equivalent to the predicate device.

- Output Frequency Measurements
- Output Power Measurements (No Load to Maximum Load)
- Tip Displacement Measurements
- Irrigation Flowrate Measurements (Ultrasound On and Flush Mode)
- Life Tests
- Vacuum Flowrate and Pressure Measurements
- Input Power Measurements
- EMI Tests
- Dielectric Tests on Mains Circuits
- Patient Current Leakage and Patient Sink Current Measurements
- Power Line Ground Leakage Measurements
- Dielectric Tests on Patient Circuits

8. Discussion of Clinical Tests Performed

N/A

9. Conclusions

Based upon an analysis of the operating characteristic specifications, Output of Engineering Tests, Hazard Analysis and Voluntary Consensus Standard Investigations, Misonix Inc. has concluded that the Alliger Ultrasonic Surgical System Model AUSS-4 is substantially equivalent to the CUSA Model 200H and the Spemby Selector Ultrasonic Surgical System.



SEP 4 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Misonix, Inc.
c/o MDI Consultants, Inc.
Ms. Susan D. Goldstein-Falk
Official Correspondent for Misonix, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K982841
Trade Name: Modification to Alliger Ultrasonic Surgical System
Model AUSS-4
Regulatory Class: Unclassified
Product Code: LFL
Dated: August 10, 1998
Received: August 12, 1998

Dear Ms. Goldstein-Falk:

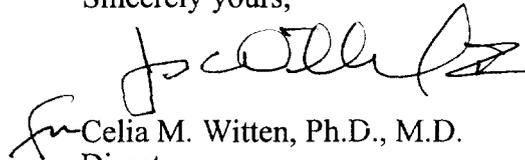
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 982841

Device Name: Alliger Ultrasonic Aspirator Model AUSS-4

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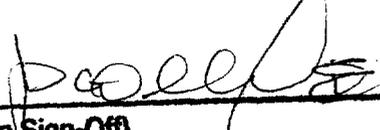
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Thoracic Surgery

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(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 General Restorative Devices K982841
 510(k) Number _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____