

K070313

510K SUMMARY – Alliger Ultrasonic Surgical System Model AUSS-7

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

1. Submitter’s Identification

Name: MISONIX, INC.
Address: 1938 New Highway, Farmingdale, NY 11735
Telephone Number: (631) 694-9555
Contact Person: Ronald R. Manna, Vice President Regulatory Affairs
Date Prepared: January 23, 2007

2. Name of Device

Proprietary Name: Alliger Ultrasonic Surgical System Model AUSS-7
Common / Usual Name: Ultrasonic Surgical System
Ultrasonic Surgical Aspirator
Classification Name: Instrument, Ultrasonic Surgical

3. Predicate Device Information

Original Device: Misonix Inc. Ultrasonic Surgical Aspirator AUSS-6, K050776

4. Device Description

The Alliger Ultrasonic Surgical System is comprised of a generator, which feeds a 22.5 kHz electrical signal to a piezoelectric crystals mounted in a hand-held handpiece; the crystals then vibrate at the same frequency. The titanium tip attached to the handpiece amplifies the vibration. Both irrigation / aspiration can be provided to introduce irrigation solution and remove fragmented material and waste liquids from the area.

5. Intended Use:

The AUSS-7 Ultrasonic Surgical System is indicated for use in the fragmentation and aspiration of both soft and hard (e.g.: bone) 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
 - Sebaceous cysts

Abdominal area

1/2

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.

Wound Care

The Misonix Inc. AUSS-7 Ultrasonic Surgical Aspirator is also indicated for use in the debridement of wounds, such as, but not limited to, burn wounds, diabetic ulcers, bedsores and vaginal ulcers, soft tissue debridement and cleansing of the surgical site in applications in which, in the physician's judgement would require the use of an ultrasonic aspirator with sharp debridement.

6. Comparison to Original Device:

The AUSS-7 is identical in its mode of operation and Indications for Use. The main difference is the controls, displays and alarms are microprocessor controlled and displayed on an LCD screen. The outer housing is also different for cosmetic purposes.

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

- 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.
- Software Validations

8. Discussions of Clinical Tests Performed

N/A

9. Conclusions

Based upon an analysis of the operating characteristic specifications, Output of Engineering Tests, Risk Analysis, and Voluntary Consensus Standard Investigations, Misonix, Inc. has concluded that the Alliger Ultrasonic Surgical System Model AUSS-7 is substantially equivalent to the AUSS-6 and introduces no new safety or efficacy concerns.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2007

Misonix Inc.
% Mr. Ronald Manna
Vice President, Regulatory Affairs
1938 New Highway
Farmingdale, New York 11735

Re: K070313

Trade/Device Name: Misonix Inc. AUSS-7 Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: April 16, 2007
Received: April 18, 2007

Dear Mr. Manna:

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.

Page 2 – Mr. Ronald Manna

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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours

A handwritten signature in black ink, appearing to read "For Mark N. Melkerson". To the right of the signature, there are handwritten initials "DGP" and "5/10/07".

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

Enclosure

EXHIBIT C

K070313

Indications for Use

Device Name: Misonix Inc. AUSS-7 Ultrasonic Surgical Aspirator System

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- Neurosurgery
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- 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
- 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.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

(Division Sign-Off)

Concurrence of GDRH, Office of Device Evaluation (ODE)
**Division of General, Restorative,
and Neurological Devices**

510(k) Number K070313

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Indications for Use (con't)

Thoracic Surgery

Limited pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and metastatectomies.

Wound Care

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Prescription Use X
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(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)