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510(k) SUMMARY - Misonix Inc. FS 1000 RF Ultrasonic Aspirator System

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

1. **Submitter's Identification**

Submitter's Name:	MISONIX INCORPORATED
Address:	1938 New Highway, Farmingdale, NY 11735
Telephone Number:	516-694-9555
Contact Person:	Ronald R. Manna
Date Prepared:	July 15, 2003

2. **Name of Device**

Proprietary Name:	Misonix Inc. FS 1000 RF Ultrasonic Surgical Aspirator System
Common/Usual Name:	Ultrasonic Surgical System Ultrasonic Surgical Aspirator
Classification Name:	Instrument, Ultrasonic Surgical

3. **Predicate Device Information**

Predicate Devices	ValleyLab CUSA® EXCEL Ultrasonic Surgical Aspirator Misonix Inc. AUSS-5 Ultrasonic Surgical Aspirator

4. **Device Description**

The Misonix Inc. FS 1000 RF Ultrasonic Aspirator System is comprised of a generator that feeds a 23 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. The system incorporates features that allow it to interface with standard electrosurgery generators (modules). By activating the output of the electrosurgery generators, RF voltage is available at the distal end of the ultrasonic cannula. This feature allows the surgeon to cauterize tissue with or without the simultaneous application of ultrasound energy.

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510(k) SUMMARY - Misonix Inc. FS 1000 RF Ultrasonic Aspirator System

5. **Intended Use:** The Misonix Inc. FS 1000 RF Ultrasonic Aspirator System is indicated for use in the fragmentation, emulsification 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
Gynecological Surgery
Thoracic Surgery
Laparoscopic Surgery
Thoracoscopic Surgery

The system may also be combined with electrosurgery using optional RF Surgery interface components.

6. **Comparison to Predicate Device** The Misonix Inc. FS 1000 RF Ultrasonic Aspirator Systemis similar in design, material and operating parameters to the CUSA® EXCEL Ultrasonic Surgical Aspirator. Although the CUSA® has a magneto-strictive transducer and the Misonix Inc. FS 1000 RF Ultrasonic Aspirator System has a piezoelectric transducer, the FDA has determined in the past that the piezoelectric handpiece is substantially equivalent to the magnetostrictive handpiece technology.

7. **Safety and Performance Data** The Misonix Inc. FS 1000 RF has been designed and tested to pass the following Voluntary Standards:

UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-2-2 Medical Electrical Equipment, Part 2: Particular Requirements for Safety of High Frequency Surgical Equipment
EN 60601-1-2:2001 Electromagnetic Compatibility
FCC Part 18 EMC Requirements

7. **Software Validation** This device contains software. The software has been validated. The validation protocol considered failure and effects analysis.

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8. **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
RF Cautery Life Tests
Dielectric Tests with RF Cautery Unit Attached
RF Cautery Unit Ouput Power Tests

9. **Discussions 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 Misonix Inc. FS 1000 RF Ultrasonic Surgical Aspirator System is substantially equivalent to the CUSA EXCEL system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2003

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

Re: K032690
Trade/Device Name: Misonix Inc. FS 1000 RF Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: August 27, 2003
Received: September 11, 2003

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.

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 (301) 594-4659. 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

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

Enclosure

Exhibit C Indications for Use Statement

510(k) Number (if known): K032690

Device Name: Misonix Inc. FS 1000 RF Ultrasonic Surgical Aspirator System

Indications For Use: The Misonix Inc. FS 1000 RF Ultrasonic Aspirator System is indicated for use in the fragmentation, emulsification and aspiration of soft tissue in the following surgical specialties:

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Thoracic Surgery
Laparoscopic Surgery
Thoracoscopic Surgery

The system may also be combined with electrosurgery using optional RF Surgery interface components.

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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032690