JAN 2 6 2006

Exhibit E 510(k) SUMMARY - Misonix Inc Sonatherm 600 Ultrasonic Lesion Generating System

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

K042096

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 14, 2004
Date Revised:	October 28, 2005

2. **Name of Device**

Proprietary Name:	Misonix Inc. Sonatherm 600 Ultrasonic Lesion Generating System
Common/Usual Name:	Ultrasonic Surgical System
Classification Name:	Instrument, Ultrasonic Surgical

. **Predicate Device Information**

Rita Medical Systems Model 500 (K983214) and 1500 RF (K993944) Generator Systems and Accessories
AFx Inc. Microwave Surgical System and Accessories (K003978)
Endocare Cryocare Surgical System (K011074).
Radionics RFG-3C RF Lesion Generator (K901540)

4. **Device Description**

Sonatherm 600 Ultrasonic Lesion Generating System is comprised of a generator, which feeds a 3 to 5 MHz electrical signal to one or more piezoelectric crystals mounted in a hand-held handpiece; the crystals then vibrate at the same frequency. A Coupling Fluid Recirculation System is provided to provide a temperature stabilized coupling/coolant fluid surrounding the Transducer crystal(s). The fluid is contained by a flexible membrane surrounding the transducer head. A user interface provides Input Controls and Output Readouts for Operator.

In operation, the Transducer Membrane is placed against the organ to be treated. When the unit is engaged, the transducer will vibrate, create

acoustic waves in the coupling fluid that then couples to the organ tissue and propagates into it. The waves converge to a focal point that concentrates the energy within a finite tissue volume. As the temperature of the tissue rises above the ablation point, the tissue necroses. The treatment head is moved under Operator control to treat a preselected volume of tissue from the focal point back to the surface of the organ.

5. **Intended Use:** The Sonatherm is indicated for the laparoscopic or intraoperative ablation of soft tissue from the ultrasound focal zone back to the surface of the targeted treatment area in General Surgery.

6. **Comparison to Predicate Device**

Sonatherm 600 Ultrasonic Lesion Generating System is similar in clinical use, safety and outcome to the Rita Medical Systems Model 500 (K983214) and 1500 RF (K993944) Generator Systems and Accessories, the AFx Inc. Microwave Surgical System and Accessories (K003978), the Endocare Cryocare Surgical System (K011074) and the Radionics RFG-3C RF Lesion Generator and accessories (K901540B). Although housed differently, all of the aforementioned devices allow the surgeon to target selected tissue for ablation in either laparoscopic or intraoperative modes and provide controlled energy input to the organ to facilitate said ablation. In the case of the Sonatherm 600, this volume is located from the focal point back to the surface of the organ. Ablated tissue may then be removed surgically or left intact for absorption and removal by the bodies normal cleansing mechanisms. Such treatment has been shown to be safe and efficacious over many decades of clinical use.

7. **Safety and Performance Data**

The Sonatherm 600 Ultrasonic Lesion Generating System has been designed to and will be 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 60601-1-2:2001 Electromagnetic Compatibility
FCC Part 18 EMC Requirements

8. **Software Validation** There is no software associated with this product.

9. **Sterilization Validations** Validation statements are contained in Exhibit J.

10. **Non-Clinical Tests for Determination of Substantial Equivalence:**

Output Frequency Measurements
Output Power Measurements
Focal Length Accuracy Measurements (Schlieren Photos)
Life Tests
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
Sterilization or Disinfection Protocol Validation for all Reusable Components
In Vitro Targeting Accuracy Measurements
Computer Modeling of Lesion Creaton vs Time and Focal Depth

11. **Conclusions**

Based upon an analysis of the operating characteristic specifications, Output of Engineering Tests, FMEA Analysis and Voluntary Consensus Standard Investigations, Misonix, Inc. has concluded that the Misonix Inc. Sonatherm 600 Ultrasonic Lesion Generating System is substantially equivalent to the Rita Medical Systems Model 500 (K983214) and 1500 RF (K993944) Generator Systems and Accessories, the AFx Inc. Microwave Surgical System and Accessories (K003978), the Endocare Cryocare Surgical System (K011074) and the Radionics RFG-3C RF Lesion Generator and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2006

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

Re: K042096
Trade/Device Name: Sonatherm 600 Ultrasonic Lesion Generating System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NTB
Dated: November 17, 2005
Received: November 17, 2005

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for

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

Enclosure

Exhibit C

510(k) Number (if known): **K042096**

Device Name: **Sonatherm 600 Ultrasonic Lesion Generating System**

Indications for Use:

The Sonatherm is indicated for the laparoscopic or intraoperative ablation of soft tissue from the ultrasound focal zone back to the surface of the targeted treatment area in General Surgery.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch for MKM

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

510(k) Number K042096