JUL - 9 2008

510(k) Summary

K070779

Sponsor's Name, Address, Phone & Fax:	MISONIX INCORPORATED 1938 New Highway, Farmingdale, NY 11735 Phone: 631 694 9555 x 123 Fax: 631 694 1322
Contact Person:	Ronald R. Manna
Date Prepared:	7/7/08
Device Trade Name	Sonatherm 600i Ultrasonic Lesion Generating System
Device Common Name:	Sonatherm 600i
Proposed Class, Classification Name and Number, and Product Code:	Class II Electrosurgical cutting and coagulation device and accessories 21 CFR 878.4400 Product Code: NTB
Predicate Devices:	Sonatherm 600 Ultrasonic Lesion Generating System, K042096 Endocare CryoCare™ Surgical System with CryoGuide™ K002615 Endocare CryoCare CS Surgical System K032333 Endocare CryoCare CS Surgical System K050347
Device Description :	The Sonatherm 600i is a modification of the previously cleared Sonatherm 600 (K 042096). The Sonatherm 600i uses the same HIFU transducer, with the same ultrasonic lesion generating power output as the Sonatherm 600. The Sonatherm 600i operates in the same manner as the Sonatherm 600.The Sonatherm 600i operates by utilizing a focused ultrasound transducer positioned at the surface of the targeted ablation area to create a thermal lesion from the focal point of the transducer back to the surface of the targeted area in an open field or laparoscopic scenario. The Sonatherm 600i incorporates three changes to the Sonatherm 600:a microprocessor controlled LCD user interface; a visually aided focal point targeting system; an integrated transducer positioning device The microprocessor controlled LCD user interface incorporates a graphical interface that makes the operation of the device easier. The integrated positioning device allows the user to verify the positioning of the Sonatherm 600i probe over the intended target volume. This reduces the chance for operator error.

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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 ablation area in General Surgery. The Sonatherm is not to be used for non-invasive ablation, i.e. leaving intervening tissue spared, and it is not indicated for the ablation of Prostate tissue
Summary of Technological Characteristics:	The Sonatherm 600i operates in the same manner as the Sonatherm 600.The Sonatherm 600i operates by utilizing a focused ultrasound transducer positioned at the surface of the targeted ablation area to create a thermal lesion from the focal point of the transducer back to the surface of the targeted area in an open field or laparoscopic scenario.
Summary of nonclinical tests	Sonatherm 600i Targeting Accuracy Test Report Thermal Mapping of Ablation Region Validation of Imaging Operation Total Acoustic Power Tests of Transducers
Summary of clinical tests	No clinical testing is required because product did not change HIFU power output or type. Note: clinical data was also not required to clear the original device.
Conclusions from nonclinical and clinical tests	Based upon an analysis of the operating characteristic specifications, Risk Analysis, and Voluntary Consensus Standard Investigations, Misonix, Inc. has concluded that the Sonatherm 600i is substantially equivalent to the predicate devices 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

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Misionix Incorporated
% Mr. Ronald Manna
VP, Regulatory Affairs
1938 New Highway
Farmingdale, New York 11735

Re: K070779
Trade/Device Name: Sonatherm 600i 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: April 9, 2008
Received: April 11, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

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

Enclosure

Indications for Use

K070779

Device Name: Sonatherm 600i 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 ablation area in General Surgery. The Sonatherm is not to be used for non-invasive ablation, i.e. leaving intervening tissue spared, and it is not indicated for the ablation of Prostate tissue.

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 Brenner

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

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