K123980

MAR 5 2013

Exhibit E 510(k) SUMMARY

Misonix SonicOne Plus Ultrasonic Wound Care System and Accessories

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:	December 20, 2012

2. **Name of Device**

Proprietary Name:	Misonix SonicOne Plus Ultrasonic Wound Care System and Accessories
Common/Usual Name:	Ultrasonic Surgical System Ultrasonic Surgical Aspirator
Name:	Low Energy Ultrasonic Wound Cleaner
C.F.R. Section	21 CFR 878.4410
Product Codes:	NRB, FQH

3. **Predicate Device Information**

Predicate Devices	SonicOne Ultrasonic Wound Care System and Accessories K112782 Misonix Inc. Alliger Ultrasonic Surgical System AUSS-7 K070313 Microtek Medical Inc. Equipment Drapes K050322

4. **Device Description** The SonicOne Plus Ultrasonic Wound Care System and Accessories 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. An irrigation unit is provided to introduce irrigation solution to the operative site. Accessories include Probe tips, Wrenches, Sterile and non

sterile Tube sets and sterile Surgical Procedure bags and sterile Handpiece Sheaths.

5. **Intended Use:** The Misonix SonicOne Ultrasonic Would Care System and Accessories are 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 judgment would require the use of an ultrasonic aspirator with sharp debridement.

6. **Comparison to Predicate Device**

SonicOne Plus Ultrasonic Wound Care System and Accessories are similar in design, material and operating parameters to the Misonix Inc. AUSS-7 Ultrasonic Surgical Aspirator and the Misonix Inc. SonicOne Ultrasonic Wound Care System

7. **Safety and Performance Data**

The Misonix SonicOne Plus Ultrasonic Wound Care System and Accessories have been designed and tested to pass the following Voluntary Standards:

UL 60601-1 2nd Edition	Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC 60601-1* 2nd Edition	Medical Electrical Equipment, Part 1: General Requirements for Safety
ISO 10993-1:2009	Biological evaluation of medical devices —Part 1: Evaluation and testing
ISO 10993-7:2008	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals
ISO 14971:2007	Medical devices -- Application of risk management to medical devices
ISO 15223-1:2007/A1:2008	Medical devices —Symbols to be used with medical device labels, labeling, and information to be supplied —Part 1: General requirements
ISO 11607:2006	Packaging for Terminally Sterilized Medical Devices
ISO 11135:2007	Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
IEC 62304: 2006	Medical Device Software-Software Life Cycle Processes
IEC 60601-1-4	General Requirements for safety-Programmable electrical medical systems
FCC Part 18	EMC Requirements

8. **Software Validation** This device contains software. Software has been cleared under FDA 510k #K070313. The, software and its documentation meets all of the requirements of the FDA guideline "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and ISO 60601-1-4.

9. **Sterilization Validations** Items supplied sterile have been validated for sterility to ANSI/AAMI/ISO 11135:1994 or latest edition and ISO 11135:2007. For items to be reprocessed, cleaning/disinfecting/sterilization instructions are validated to insure appropriate level of cleaning/disinfection/sterilization when instructions are followed.

10. 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
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

11. Discussions of Clinical Tests Performed

The FDA has cleared all indications for use in the predicates. As such, no additional clinic data was obtained in anticipation of this submission.

12. Conclusions

Misonix Inc. can state that the SonicOne Plus Ultrasonic Wound Care System and Accessories is substantially equivalent in Mode of Operation, Hardware Design and Output Parameters to the Misonix Inc. AUSS-7 and the SonicOne Ultrasonic Wound Care System. Based upon the system and hardware validations described herein, the Misonix Inc. believes the SonicOne Plus Ultrasonic Wound Care System and Accessories poses no new issues of safety or efficacy when used for tissue ablation during wound debridement.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center– WO66-G609
Silver Spring, MD 20993-0002

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

Letter dated: March 5, 2013

Re: K123980
Trade/Device Name: SonicOne Plus Ultrasonic Wound Care System and Accessories
Regulation Number: 21 CFR 878.4410
Regulation Name: Low energy ultrasound wound cleaner
Regulatory Class: II
Product Code: NRB, FQH
Dated: February 11, 2013
Received: February 14, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K123980

Exhibit C INDICATIONS FOR USE STATEMENT

Device Name: SonicOne Plus Ultrasonic Wound Care System and Accessories

The Misonix SonicOne Ultrasonic Would Care System and Accessories are 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 judgment would require the use of an ultrasonic aspirator with sharp debridement.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.03.05 09:58:35 -05'00'

for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number K123980