Misonix, Inc.
Ronald Manna
VP, Regulatory Affairs
1938 New Highway
Farmingdale, New York 11735

June 8, 2021

Re: K041058
Trade/Device Name: Misonix Inc. Lysonix 2000/3000 Ultrasonic Surgical Aspirator Systems
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Ronald Manna:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 17, 2004. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

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

Re: K041058
Trade/Device Name: Misonix Inc. LYSONIX 2000/3000 Ultrasonic Surgical Aspirator System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: April 15, 2004
Received: April 23, 2004

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

K041058

Exhibit C Indications for Use Statement

Device Name: Misonix Inc. LYSONIX 2000/3000 Ultrasonic Surgical Aspirator System

LYSONIX 2000/3000 Systems are indicated for the liquefaction and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery and Gynecological Surgery Applications. It is also indicated for the liquefaction and aspiration of localized subcutaneous fatty deposits for the purposes of aesthetic body contouring.

Prescription Use ✓ 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 K041058

MAY 17 2004

K041058
p1/2

Exhibit E 510(k) SUMMARY - Misonix Inc. LYSONIX 2000/3000Ultrasonic Aspirator Systems

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:	April 1, 2004

2. **Name of Device**

Proprietary Name:	Misonix Inc. LYSONIX 2000/3000 Ultrasonic Surgical Aspirator Systems
Common/Usual Name:	Ultrasonic Surgical System Ultrasonic Surgical Aspirator
Classification Name:	Instrument, Ultrasonic Surgical

3. **Predicate Device Information**

Predicate Devices	Mentor Contour Genesis Ultrasound Assisted Tissue Removal System K004005 SoundVaser System, Sound Surgical Technologies Inc. K022051

4. **Device Description**

LYSONIX 2000/3000 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. An irrigation / aspiration unit is provided to introduce irrigation solution and remove fragmented material and waste liquids from the area.

K041058
P2/2

5.	**Intended Use:**	LYSONIX 2000/3000 System is indicated for the liquefaction and aspiration of soft tissues in General Surgery, Plastic and Reconstructive Surgery and Gynecological Surgery Applications. It is also indicated for the liquefaction and aspiration of localized subcutaneous fatty deposits for the purposes of aesthetic body contouring.
6.	**Comparison to Predicate Device**	LYSONIX 2000/3000 Systems is similar in design, material and operating parameters to the SoundVaser Ultrasonic Aspirator. The Sound Vaser is an Ultrasonic Aspirator System that features Pulsed Output Technology. It has an Ultrasonic Lipoplasty Indication for Use as well. In addition, LYSONIX 2000/3000 Systems are substantially equivalent to the Mentor Contour Genesis System in terms of Theory of Operation, Indications and Operating Specifications with the exception that the Mentor Contour Genesis System (K004005) does not incorporate Pulsed Output Technology.

7. **Safety and Performance Data**

The Misonix Inc. LYSONIX 2000/3000 SYSTEMS have 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 60601-1-2:1993 Electromagnetic Compatibility (LySonix 2000)
EN 60601-1-2:2001 Electromagnetic Compatibility (LySonix 3000)
FCC Part 18 EMC Requirements

7.	**Software Validation**	This device does not contain software.
8.	**Sterilization Validations**	Validation reports are contained in Exhibit J.