February 3, 2022

Omnisonics Medical Technologies
Anne Kulis
VP, Quality, Regulatory, Clinical Affairs
66 Concord Street, Suite A
Wilmington, Massachusetts 01887

Re: K083335
Trade/Device Name: Modified Omniwave Endovascular System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Anne Kulis:

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 December 15, 2008. Specifically, FDA is updating this SE Letter as an administrative correction 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 Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2022.02.03 14:28:48 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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

DEC 15 2008

OmniSonics Medical Technologies, Inc.
c/o Ms. Anne Kulis
66 Concord Street, Suite A
Wilmington, MA 01877

Re: K083335
Trade/Device Name: Modified Omniwave Endovascular System
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II
Product Code: KRA
Dated: November 11, 2008
Received: November 12, 2008

Dear Ms. Kulis:

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) 276-0120. 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 Biometrics' (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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083335

Device Name: Modified Omniwave Endovascular System

Indications For Use:

The Modified Omniwave Endovascular System is indicated for use in the infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature and for removal of thrombi from the peripheral vasculature.

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)

Donna R. Vochmer

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K083335

DEC 15 2008

510(k) Summary
Modified Omnisonics Omniwave Endovascular System

510(k) Number: K083335

Submitter: OmniSonics Medical Technologies, Inc.
66 Concord Street
Wilmington, MA 01887
Phone: 978-657-9980

Contact Person: Anne M. Kulis, VP QA, RA & CA

Date Prepared: 11/01/2008

Trade Name: Modified Omniwave Endovascular System

Classification Name: CFR §870.1210, Catheter, Continuous Flush

Predicate Device: Omniwave Endovascular System K071762

Device Description:
The Modified Omniwave Endovascular System is comprised of two major components: (1) the sterile, single use Kit, and (2) the multi-use Generator.

Intended Use:
The Modified Omniwave Endovascular System is indicated for use in the infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature and for removal of thrombi from the peripheral vasculature.

Summary of Technological Characteristics of the Applicant Device Compared to the Predicate Device:
The technological characteristics of the applicant device are substantially equivalent to the predicate device with respect to device classifications, intended use, indications for use, target population, product design, materials, packaging, labeling, sterilization and product performance.

Support of Substantial Equivalence:
Both the applicant and predicate device treat the same patient population and have the same intended use and indication for use. Product testing has demonstrated that the applicant device is substantially equivalent to the predicate devices.

Conclusion:
The Modified Omniwave Endovascular System is substantially equivalent to the predicate device.