

SEP - 1 2004

Section XI**510(k) Summary
Resolution® Thrombectomy System**

510(k) Number: _____

Submitter: OmniSonics Medical Technologies, Inc.
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Contact Person: Anne M. Kulis
Vice President Quality, Regulatory & Clinical Affairs

Date Prepared: June 18, 2004

Trade Name: Resolution Thrombectomy System

Classification Name: CFR §870.5151, Embolectomy Catheter

Predicate Devices: **Cordis Hydrolyser** – K983534, K990771
Edwards Thrombex PMT System – K993816
Arrow-Trerotola PTD – K970080, K990829

Device Description:

The Resolution Thrombectomy System is a portable acoustic energy system for the treatment of thrombosed synthetic dialysis access grafts. The system is comprised of three major components: (1) the disposable Resolution 360° Therapeutic Wire, (2) the reusable Handpiece/Cable Assembly, and (3) the multi-use Generator. Accessories include the Resolution Torque Wrench and Resolution Irrigation Tubing Set.

Intended Use:

The OmniSonics Resolution Thrombectomy System is intended for use in the treatment of thrombosed synthetic dialysis access grafts.

Summary of Technological Characteristics of the Applicant Device Compared to the Predicate Device:

There are no significant technological differences between the applicant device and the predicate devices. The technological characteristics of the Resolution Thrombectomy System are substantially equivalent to the predicate devices with respect to indications for use, sterilization methods, product design, materials, labeling, packaging, and principles of operation.

Support of Substantial Equivalence:

It has been demonstrated through clinical studies that the Resolution Thrombectomy System is substantially equivalent to the predicate devices with respect to removal of thrombus within synthetic dialysis access grafts. Additionally, the results of mechanical bench testing, biocompatibility testing and *in vivo* animal testing support that the Resolution Thrombectomy System is substantially equivalent to the predicate devices.

Conclusion:

The Resolution Thrombectomy System is substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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OmniSonics Medical Technologies, Inc.
c/o Anne M. Kulis
66 Concord Street, Suite A
Wilmington, MA 01887

Re: K041705
Resolution[®] Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: DXE
Dated: June 22, 2004
Received: June 23, 2004

Dear Ms. Kulis:

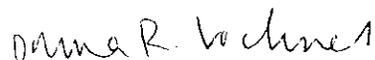
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Office of Compliance at (301) 594-4646. 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/dsma/dsmamain.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): K041705

Device Name: Resolution[®] Thrombectomy System

Indications For Use:

The Omnisonics Resolution[®] Thrombectomy System is intended for use in the treatment of thrombosed synthetic dialysis access grafts.

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)

Diana R. Vechner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041705