

OmniSonics Medical Technologies, Inc

Robert A Rabiner
President

K993628

DEC 15 1999

**510K Summary
OmniSonics Ultrasonic Probes**

1. **Sponsor Name**

OmniSonics Medical Technologies
14 Equestrian Drive
North Reading, MA 01864

Contact Individual: Debbie Iampietro
QRC Consulting Associates
7 Tiffany Trail
Hopkinton, MA 01748

2. **Device Name**

Proprietary Name: OmniSonics Ultrasonic Probes
Common/Usual Name: Ultrasonic Aspiration Device
Classification Name: Ultrasonic Aspiration Device

3. **Identification of Predicate or Legally Marketed Device**

The OmniSonics Ultrasonic probes are substantially equivalent to the following predicate devices: Sonokinetics SONOTOME System (K99XXXX) and Valleylabs Inc. CUSA® 200 System (K853143, K864983, K884412, K884413, K894600, K910696) and CUSA EXCEL System (K981262).

4. **Device Description**

Principle of Operation

The OmniSonics Ultrasonic probes work in conjunction with the OmniSonics Ultrasonic Generator. The generator creates a specific electrical signal that is directed into the OmniSonics ultrasonic handle. The signal is converted into an ultrasonic motion within the handle and this motion is transferred to the ultrasonic probe.

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The ultrasonic energy in contact with the probe causes a specifically defined motion to occur on the probe shaft. The motion of the probe in contact with the tissue causes a localized cavitation, and immediate destruction of the tissue in contact with the probe. Cavitation is caused by the motion of the probe within water and in contact with tissue.

The motion of the probe causes the formation of microbubbles to be formed. The upstroke of the probe causes the formation of the bubble behind the probe, the downstroke causes the collapse of the bubble and a small localized shock wave. This focused wave formed at the tip of the probe causes a localized and focused shock wave to be formed which impinges upon the tissue and breaks off the most least tightly bound tissue layer. The action is limited to a specific contact area of the probe upon the tissue, and does not travel beyond these contact points.

Device Configuration and Materials

The OmniSonics Ultrasonic Probes are constructed of titanium and are all specifically designed for use and operation with the OmniSonics Ultrasonic Surgical System.

The specifications of the proposed OmniSonics Ultrasonic Probes are the following:

Diameter Exterior	1 mm – 10 mm
Diameter Interior	.5 mm - 8 mm
Length	10 mm – 30 mm

5. Intended Use

The OmniSonics Ultrasonic Probes are used in conjunction with the OmniSonics Ultrasonic Surgical System to utilize ultrasonic energy for the removal of tissue. The intended use of the device is the breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic.

The OmniSonics Ultrasonic Probes are designed to be introduced through natural body cavities or surgical incisions through introducers, needles or trocars, catheters, sheaths or other devices with lumens having an inside diameter larger than the outside diameter of the probe.

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6. Comparison of Technological Characteristics

The OmniSonics Ultrasonic probes are substantially equivalent to the following predicate devices: Sonokinetics SONOTOME System (K990572) and Valleylabs Inc. CUSA® 200 System (K853143, K864983, K884412, K884413, K894600, K910696) and CUSA EXCEL System (K981262).

Ultrasonic aspiration of tissue through hollow titanium needles has been a part of the U.S. medical landscape since the 1960s. As such, the predicate devices to which the OmniSonics Ultrasonic Probes is substantially equivalent in intended use are based on a well developed technology.

The intended use of the OmniSonics Ultrasonic Probes are the same as that of other manufactures of ultrasonic probes in that they are intended for the breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic.

The OmniSonics Ultrasonic Probes have similar technological characteristics to and similar applications as the predicates Sonokinetics SONOTOME System and CUSA® 200 System, in that they are all metal alloy instruments that are attached to an ultrasonic handle providing the ultrasonic energy and motion to the probe to cause a destruction of contacted tissues. All of the devices on the market offer various configurations, lengths, diameters, use an external ultrasonic handpiece as the source of energy and are made of either titanium, stainless steel. The OmniSonics tip does not raise new questions of safety and effectiveness.

7 Performance Testing

The OmniSonics Ultrasonic Probes are tested in compliance with IEC 60601.

The materials used in the manufacture of the OmniSonics Ultrasonic Probes are biocompatible.

The OmniSonics Ultrasonic Probes are sterilized to an SAL of 10^{-6} in accordance with AAMI guidelines for ETO sterilization.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OmniSonics Medical Technologies, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K993628
Trade Name: OmniSonics Ultrasonic Probes
Regulatory Class: II
Product Code: LFL
Dated: October 23, 1999
Received: October 27, 1999

Dear Ms. Iampietro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

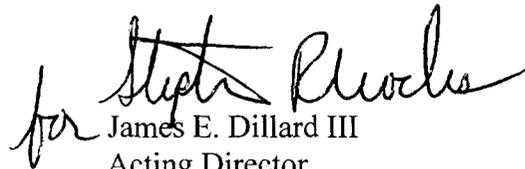
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Ms. Debbie Iampietro

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for *James E. Dillard III*

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 9 9 3 6 2 8

Device Name: OmniSoncis Ultrasonic Probes

Indications For Use:

The intended use of the OmniSoncis Ultrasonic Probes is the breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and Reconstructive surgery, Orthopedic, GYN, Thoracic. The OmniSoncis Ultrasonic Probes are used in conjunction with the OmniSoncis Ultrasonic Surgical System.

The OmniSoncis Ultrasonic Probes are designed to be introduced through natural body cavities or surgical incisions through introducers, needles or trocars, catheters, sheaths or other devices with lumens having an inside diameter larger than the outside diameter of the probe.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 9 9 3 6 2 8

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