K991377

OmniSonics Medical Technologies
14 Equestrian Drive
No. Reading, MA 01864

**510K Summary**
**OmniSonics Medical Technologies**
**Flexible Fiber Optic Endoscope and Coupler**

1. Sponsor Name

OmniSonics Medical Technologies
14 Equestrian Drive
North Reading, MA 01864

Telephone: (978) 664 8440
Contact Individual: Debbie Iampietro

2. Device Name

Proprietary Name: OmniSonics Flexible Fiberoptic Endoscope and Coupler
Common/Usual Name: Endoscope
Classification Name: Endoscope and accessories

3. Identification of Predicate or Legally Marketed Device

The OmniSonics Endoscopes are substantially equivalent to several legally marketed devices including:

Galileo Endoscopes K962116
Galileo Disposable Endoscopes K981928
Imagyn Laparascope K944079
Saratoga Medical K943593
Clarus Murphy Scope K962255

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4. Device Description

The OmniSonics Endoscopes are fiber optic designed endoscopes offered in a variety of lengths, diameters and configurations for user convenience. The fiberoptic endoscope functions by light being transmitted from a standard external high intensity light source through illumination fibers to the distal tip of the scope. The image is transmitted via a fiber-imaging bundle to an eyepiece. The image is viewed directly or transmitted through a video camera to a monitor.

The device is provided with a reusable coupler and is also compatible with other standard couplers currently marketed.

5. Intended Use

The OmniSonics Endoscopes are fiber optic endoscopes intended for visualization of body cavities, hollow organs, and canals. The OmniSonics Endoscopes are designed to be introduced through natural body cavities or surgical incisions through introducers, needles or trocars, catheters, sheaths of other devices with lumens having an inside diameter larger than the outside diameter of the endoscope. The OmniSonics Endoscopes are indicated for the following applications:

Ureteroscopy
Bronshoscopy
Thoracoscopy
NasopharyngoscopySinuscopy
General laparoscopy
Urology
Gynecological

6. Comparison of Technological Characteristics

The intended uses of each of the devces are identical in that they are all fiberoptic endoscopes intended for visualization of body cavities, tissues, organs or canals. The OmniSonics Endoscopes are substantially similar in design, technological characteristics and materials to the above cited predicates. All of the devices on the market offer various configurations, lengths, diameters, use an external light source and are made of either stainless steel or polyamide.

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7 Performance Testing

The OmniSoncis Endoscopes conform to IEC 60601-2-18
All materials used are biocompatable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

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

Re: K991377
Trade Name: Flexible Fiber Optic Endoscope and Coupler
Regulatory Class: II
Product Code: GCJ
Dated: April 20, 1999
Received: April 21, 1999

Dear Ms. Iampietro:

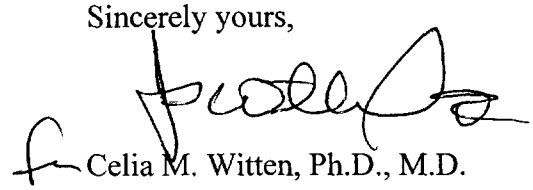
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991377

Device Name: OmniSoncis Flexible Fiber Optic Endoscope and Coupler

Indications For Use:

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(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)

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