



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

OmniSonics Medical Technologies, Inc.  
Ms. Debbie Iampietro  
QRC Consulting  
7 Tiffany Trail  
Hopkinton, MA 01748

JUL 27 2015

Re: K993445  
Trade/Device Name: Endoscopic Deflector  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: GCM  
Dated (Date on orig SE ltr): October 8, 1999  
Received (Date on orig SE ltr): October 12, 1999

Dear Ms. Iampietro,

This letter corrects our substantially equivalent letter of December 6, 1999.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Benjamin R. Fisher -S**

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K993445

Device Name: OmniSoncis Endoscopic Deflector

Indications For Use:

The OmniSoncis Endoscopic Deflector is designed to assist in the placement and deflection of small diameter malleable instruments, catheters and endoscopes used in surgical procedures in body cavities, hollow organs and canals.

The OmniSoncis Endoscopic Deflector is designed to be introduced through natural body openings, surgical incisions and through introducers, needles, trocars, catheters, sheaths and other devices with lumens having an inside diameter larger than the outside diameter of the OmniSoncis Endoscopic Deflector shaft selected. The OmniSoncis Endoscopic Deflector is sold sterile and is intended for single patient use. The OmniSoncis Endoscopic Deflector is indicated for the following applications:

- Ureteroscopy
- Thoracoscopy
- Nasopharyngoscopy Sinuscopy
- General laparoscopy
- Urology
- Gynecology
- Bronchoscopy

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR Over-The-Counter Use

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K 993445

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***OmniSonics Medical Technologies, Inc***

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Robert A Rabiner  
President

DEC - 6 1999

K993445

**510K Summary  
OmniSonics Endoscopic Deflector**

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 Endoscopic Deflector  
Common/Usual Name: Endoscope  
Classification Name: Endoscope and accessories

3. Identification of Predicate or Legally Marketed Device

The OmniSonics Endoscopic Deflector is substantially equivalent to several legally marketed devices in intended use, design and technological characteristics. Those devices to which it is substantially equivalent are: Omnisonics Endoscopes (K991377), Karl Storz Hystero-Fiberscope (K990411), Karl Storz Laser Application Instrument (K# unknown), and the Naviport Deflectable Tip Guiding Catheter (K974683).

4. Device Description

Principle of Operation

The OmniSonics Endoscopic Deflector assists in the delivery of small diameter flexible; instruments, catheters, probes, and endoscopes. The device deflects these instruments to aid in the direction and delivery of the product to a specific surgical site that is not in line with the axis of the instrument. The purpose of the OmniSonics Endoscopic Deflector is to provide a means to deliver small diameter instruments to areas that would be difficult to access with a straight instrument.

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Robert A Rabiner  
President

The OmniSonics Endoscopic Deflector works in a similar fashion to steerable endoscopes. This instrument is different in that it only contains lumens for the introduction of ancillary instrumentation and does not possess an integral visualization system. The user must insert all of the additional capabilities desired through the OmniSonics Endoscopic Deflector central lumen.

Products that are capable of working with the OmniSonics Endoscopic Deflector are flexible, malleable or bendable and must be capable of obtaining a bend radius of 30 mm or less. They must also have an outer diameter compatible with the inner diameter of the unit selected. The actual deflection produced at the end of the device will depend upon the stiffness of the inserted instrument.

**Device Configuration and Materials**

The OmniSonics Deflector is constructed with the following major components:

- |                    |  |
|--------------------|--|
| Outer sheath tube: | A rigid, stainless steel tube that provides rigidity for insertion into the body   |
| Deflection tube:   | A flexible, polyurethane, kink resistant tube that bends when the deflection handle is activated.  |
| Deflection wire:   | A stainless steel wire that pulls the tip of the deflection tube to cause deflection.  |
| Deflection handle: | An ABS handle that has mechanisms for rotation of the shaft, articulation of the deflection tube, movement of the inserted device in and out and sealing of the inserted device. |

**5. Intended Use****Intended use**

The OmniSonics Endoscopic Deflector is a device designed to assist in the placement and deflection of small diameter malleable instruments, catheters and endoscopes used in surgical procedures in body cavities, hollow organs and canals.

The OmniSonics Endoscopic Deflector is designed to be introduced through natural body openings, surgical incisions and through introducers, needles, trocars, catheters, sheaths and other devices with lumens having an inside diameter larger than the outside diameter of the OmniSonics Endoscopic Deflector shaft selected. The OmniSonics Endoscopic Deflector is sold sterile and is intended for single patient use. The OmniSonics Endoscopic Deflector is indicated for the following applications:

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Ureteroscopy  
Thoracoscopy  
Nasopharyngoscopy  
Sinuscopy  
General laparoscopy  
Urology  
Gynecology  
Bronchoscopy

6. **Comparison of Technological Characteristics**

All of the predicate devices are similar in intended use, design and materials. The proposed OmniSonic Endoscopic Deflector is made materials that have been widely used in other endoscopic applications and have a long history of use.

All of the predicate devices offer various configurations, lengths, diameters, and have varying degrees of deflection. The proposed OmniSonic Endoscopic Deflector's specifications are similar to the parameters established by the predicate devices and similar to other devices in the medical device industry.

The technological characteristics used in the proposed OmniSonic Endoscopic Deflector to assist in the placement, deflection and/or articulation of medical devices into body cavities, hollow organs and canals are inherent in the predicate Karl Storz Laser Application Instrument and the Naviport Deflectable Tip Guiding Catheter.

The difference in technological characteristics is in the generic application of the OmniSonic Endoscopic Deflector. Each of the predicates and devices cited for similarities in deflection capability are "dedicated" to the devices they accompany. The OmniSonic Endoscopic Deflector is not dedicated to one instrument or corporate family of instruments. It is to be used with other devices that are compatible to its design characteristics as identified in its labeling.

Since the OmniSonic Endoscopic Deflector is the same in intended use, design, principle of operation, technological characteristics, and materials as the predicate devices, the OmniSonic Endoscopic Deflector does not raise any new safety and efficacy concerns when compared to these similar legally marketed devices. Therefore, the OmniSonic Endoscopic Deflector is substantially equivalent to these existing devices.

7 **Performance Testing**

The OmniSonic Deflector conforms to IEC 60601-18  
All materials used are biocompatible

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