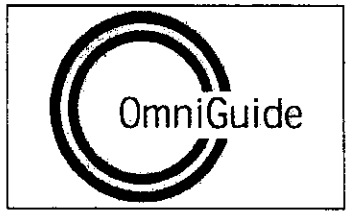

DEC 1 4 2007

K073409

510(k) Summary

Submitter:	OmniGuide, Inc. One Kendall Square, Building 100 3rd Floor Cambridge, MA 02139
Contact Person:	Douglas W. Woodruff
Telephone:	617-551-8404
Fax:	617-551-8445
Proprietary Name:	OmniGuide Sterile WaveGuide Adapter System
Common Name:	CO_2 Laser Powered Surgical Instrument
Classification:	878.4810
Product Code:	GEX
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology.

Substantial Equivalence Claimed To:

K062423, OmniGuide Beam Delivery System

Description:

Intended Use:

The OmniGuide Sterile WaveGuide Adapter System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology, otorhinolaryngology, gastroenterology, neurosurgery, urology, and pulmonology, and can be used in open surgical procedures as well as endoscopic minimally invasive procedures in conjunction with rigid or flexible endoscopes, such as in laryngoscopy, gastroscopy, colonoscopy, laparoscopy, thoracoscopy, hysteroscopy and bronchoscopy.

The indications for use for which the delivery system is used for are dependent upon the cleared indications for use of the laser system and those laser system accessories to which it is attached.

Summary of Technological Characteristics:

The OmniGuide Sterile WaveGuide Adapter System connects a hospitals CO_2 laser to the OmniGuide WaveGuide Fibers. The additional filter and autoclave sterilization of the adapter and hose allows for use in sterile surgical procedures.

The output tube and gas hose will be sold non-sterile and the hospital will autoclave sterilize. The filter element may be provided as a gamma sterilized device (high Pressure option) or as a non sterile device for autoclave sterilization. The low pressure filter may be autoclave sterilized or provided sterile at the end users request. See section S for sterilization validation activites.

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Performance Data:

Non-clinical Performance Data:

The OmniGuide Sterile WaveGuide Adapter System performance characteristics have been evaluated through testing and analysis of laser power output and beam quality. This type of testing complies with the respective section of the FDA Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (1995) and is similar to the predicate device tests. The performance of the OmniGuide Sterile WaveGuide Adapter System and the related parameters of the predicate device is comparable.

Clinical Performance Data:

Formal clinical trials were not deemed necessary as the device is using the same technology and intended use as the predicate device.

Conclusions Drawn from Tests and Analysis:

The intended use and major performance parameters (energy transmission levels and beam quality) of the OmniGuide Sterile WaveGuide Adapter System are similar or equivalent to the characteristics of above mentioned legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

OmniGuide, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

Re: K073409
Trade/Device Name: OmniGuide Sterile WaveGuide Adapter System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 3, 2007
Received: December 4, 2007

Dear Mr. Job:

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) 276-0115. 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 Biometric's (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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not yet assigned K073409

Device Name: OmniGuide Sterile WaveGuide Adapter System

Indications For Use:

The OmniGuide Sterile WaveGuide Adapter System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology, otorhinolaryngology, gastroenterology, neurosurgery, urology, and pulmonology, and can be used in open surgical procedures as well as endoscopic minimally invasive procedures in conjunction with rigid or flexible endoscopes, such as in laryngoscopy, gastroscopy, colonoscopy, laparoscopy, thoracoscopy, hysteroscopy and bronchoscopy.

The indications for use for which the delivery system is used for are dependent upon the cleared indications for use of the laser system and those laser system accessories to which it is attached.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, ~~Office of Device Evaluation~~ (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of __1___

510(k) Number K073409