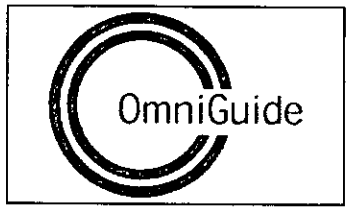
K093451



NOV 20 2009

510(k) Summary

Submitter:	OmniGuide, Inc. One Kendall Square, Building 100 3rd Floor Cambridge, MA 02139
Contact Person: **Telephone:**	Douglas W. Woodruff 617-551-8404
Fax:	617-551-8445
Proprietary Name:	OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss Tip
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:

K070157, OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber
K073313, OmniGuide BeamPath CO_2 Mark III WaveGuide Fiber With Low Profile Tip

Description:

The OmniGuide OmniGuide BeamPath CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss Tip is an accessory for CO_2 laser systems. It consists of a flexible fiber assembly that delivers CO_2 laser energy that enables minimally invasive surgery. OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss metal tip is supplied sterile and is intended for single procedure use in conjunction with the OmniGuide Laser Adapter.

Intended Use:

The OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss Tip 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 device consists of an optical fiber assembly. The main functional component of the fiber assembly is a photonic bandgap reflector lining its hollow core that reflects and thereby guides CO_2 laser energy and an internally coated, stainless steel waveguide distal tip. The fiber assembly is 1 to 2 m long and transmits at the CO_2 laser emission wavelength of 10.6 μm. The fiber has 14 mm long, internally coated, stainless steel tip that is coated internally and acts as an efficient continuation of the waveguide. The new tip configuration reduces tip heating allowing the fiber to be used in continuous wave mode without heating the tip.

Performance Data:

Non-clinical Performance Data: The OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low Profile /Low Loss Tip 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 OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss Tip and the related parameters of the predicate devices are 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 devices.

Conclusions Drawn from Tests and Analysis: The intended use and major performance parameters (energy transmission levels and beam quality) of the OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss Tip 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 20 2009

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

Re: K093451
Trade/Device Name: OmniGuide BeamPath CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss Tip
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 4, 2009
Received: November 5, 2009

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

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

Device Name: OmniGuide BeamPath CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss Tip

Indications For Use:

The OmniGuide Beam Path CO_2 Mark III WaveGuide Fiber with Low Profile/Low Loss Tip 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___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

neil hfdh for mta

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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510(k) Number K093451