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AUG 12 2008

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 BeamPath® Fiber Optic HandPiece System and Sterilization Tray
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:

K952006, ACCU-Beam Fiber Optic Handpeice
K040223 PolyVac Surgical Instrument Delivery System

Description:

The OmniGuide BeamPath® Fiber Optic HandPiece System and Sterilization Tray is indicated for use in conjunction with OmniGuide's waveguide fibers.

The objectives of the hand-piece are to enable precision control and to stabilize surgeon hand motion. The waveguide fiber is inserted through the proximal end of the hand-piece and fixated so that it is observed at the hand-piece's distal tip. The surgeon wields the hand-piece as a pencil, and advances the hand-piece so that its distal tip is in close proximity to the target tissue to exert the desired effect of the waveguide fiber: incision, excision, ablation, vaporization and coagulation. The surgeon may use the hand-piece distal tip in either non-contact mode or contact mode, and may use the distal tip to enable tissue manipulation.

The sterilization tray is purchased from SYMMETRY MEDICAL USA INC. and sold as a storage and sterilization tray for use with the OmniGuide Fiber Optic Handpieces.

Intended Use:

The OmniGuide BeamPath® Fiber Optic HandPiece System and Sterilization Tray is indicated for use in conjunction with OmniGuide's waveguide fibers to enable the surgeon to perform 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.

Summary of Technological Characteristics:

The handpieces consist of a handle and sealing cap consisting of either SS or aluminum, a silicone rubber fiber gripper and a lumen to guide the fiber made of SS hypodermic tubing. The handle/lumen are welded or adhesive bonded to for the unit. Lumen may be bent or straight to facilitate the aiming of the fiber. The tip is may be beveled or straight to improve the fiber visibility, fiber tip protection and blunt dissection.

Performance Data:

Non-clinical Performance Data: OmniGuide BeamPath® Fiber Optic HandPiece System and Sterilization Tray performance characteristics have been evaluated through testing and bench top testing. The handpieces are used to allow the physician to manipulate the flexible fiber through a surgical endoscope . The performance of the OmniGuide BeamPath® Fiber Optic HandPiece and similar related parameters of predicate device are comparable.

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

Conclusions Drawn from Tests and Analysis: The intended use and major performance parameters of the OmniGuide BeamPath® Fiber Optic HandPiece System and

Sterilization Tray are similar or equivalent to the characteristics of above mentioned legally marketed device. The sterilization tray used is the identified predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2008

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

Re: K081939
Trade/Device Name: OmniGuide BeamPath® Fiber Optic HandPiece System and Steril
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: July 26 2008
Received: July 28, 2008

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

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Indications for Use

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

Device Name: OmniGuide BeamPath® Fiber Optic HandPiece System and Sterilization Tray

Indications For Use:

The OmniGuide BeamPath® Fiber Optic HandPiece System and Sterilization Tray is indicated for use in conjunction with OmniGuide's waveguide fibers to enable the surgeon to perform 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.

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)

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

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