MAY - 9 2005

K050541

510(k) Summary

Submitter: OmniGuide Communications Inc.
One Kendall Square, Building 100 3rd Floor
Cambridge, MA 02139

Contact Person: Irina Kulinets
Telephone: 617-551-8404

Fax: 617-551-8445

Proprietary Name: OmniGuide BeamPath CO_2 Mark I Laser Beam Delivery 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:

K992472 Clinicon SureGuide CO_2 Laser Beam Delivery System.
K014048 Clinicon Universal WaveGuide Handpiece and Fiber Tips
K924664 Surgilase Fiberlase CO_2 Laserwave Guide
K921671 Surgilase Fiberlase V CO_2 Laser Waveguide
K896478 Luxar LX-20 Minilase CO_2 Surgical Laser
K031440 Cynosure Smart CO_2 Medical Laser System
K963189 ERBE APC 300 Argon Plasma Coagulator
K032969 Helica "TC" Laparoscopic Cutting and Cauterizing Accessories

Description:

The OmniGuide BeamPath CO_2 Mark I Laser Beam Delivery System is an accessory for CO_2 laser systems that can be retrofitted to Luxar LX-20 or Lumenis NovaPulse laser systems. It consists of an adapter and a fiber assembly that propagate CO_2 laser beams. The OmniGuide BeamPath CO_2 Mark I Fiber Assembly is supplied sterile and is intended for single procedure use.

Intended Use:

The OmniGuide BeamPath CO_2 Mark I Laser Beam Delivery System is intended for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues

The indications for use for which the delivery system is used 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 contains the optical fiber assembly and the adapter for connecting the fiber to the laser. 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. The fiber assembly is 1.5 m or 2.0 m long and transmits at the CO_2 laser emission wavelength of 10.6 µm.
The adapter links the fiber assembly and the CO_2 laser.

Performance Data:

Non-clinical Performance Data: The OmniGuide BeamPath CO_2 Mark I Laser Beam Delivery 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 BeamPath CO_2 Mark I Laser Beam Delivery System and related parameters of predicate devices (as specified in comparison table) are comparable. The OmniGuide BeamPath CO_2 Mark I Fiber Assembly has passed biocompatibility testing as performed by an independent laboratory in accordance with ISO 10993-1:2003 Standards.

Clinical Performance Data: Formal clinical trials were not deemed necessary as the device is using the same technology and intended use as predicate devices. However, the device was used in a compassionate use per FDA permission. No adverse effects were noticed, the device performed as intended.

Conclusions Drawn from Tests and Analysis: The intended use and major performance parameters (energy transmission levels and beam quality) of the OmniGuide BeamPath CO_2 Mark I Laser Beam Delivery System are similar or equivalent to same 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

MAY - 9 2005

Ms. Irina Kulinets
Director Regulatory Affairs and Quality Assurance
OmniGuide Communications
One Kendall Square, Building 100 3rd Floor
Cambridge, Massachusetts 02139

Re: K050541
Trade/Device Name: OmniGuide BeamPath CO^2 Mark I Laser Beam Delivery System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Regulatory Class: II
Product Code: HQF
Dated: February 25, 2005
Received: March 2, 2005

Dear Ms. Kulinets:

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 Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting 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): K050541

Device Name: OmniGuide BeamPath CO2 Mark I Laser Beam Delivery System

Indications For Use:

The OmniGuide BeamPath CO2 Mark I Laser Beam Delivery System is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues, in the medical specialties of general and plastic surgery, oral / maxillofacial surgery, dentistry, dermatology, endoscopic and open surgical procedures related to gynecology, otorhinolaryngology, gastroenterology, neurosurgery, pulmonary surgery for surgical and aesthetic applications.

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

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

K050541

Prescription Use _Yes_____ AND/OR Over-The-Counter Use __No_____
(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)