K062423

SEP 2 1 2006

# 510(k) Summary

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| **Submitter:** | OmniGuide, Inc.<br>One Kendall Square, Building 100 3rd Floor<br>Cambridge, MA 02139 |
| **Contact Person:**<br>**Telephone:** | Douglas W. Woodruff<br>617-551-8404 |
| **Fax:** | 617-551-8445 |
| **Proprietary Name:** | OmniGuide BeamPath 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:**

K050541, Omniguide Beam Path $CO_2$ Mark I Laser Beam Delivery System

**Description:**

The OmniGuide Beam Delivery System is an accessory for $CO_2$ laser systems. It consists of an adapter and a fiber assembly that propagate $CO_2$ laser beams. The OmniGuide Beam Delivery System Beampath 100 Handpeice Fiber is supplied sterile and is intended for single procedure use. The Beam Delivery System Adapter is provided non sterile for multiple uses. The Adapter will be configured to attach to specific $CO_2$ laser configurations

**Intended Use:**

The OmniGuide Beam Delivery System is intended for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intraoral tissues.

**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 1.0 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 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 Beam Delivery System and related parameters of predicate devices (as specified in comparison table) 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 devices.

**Conclusions Drawn from Tests and Analysis:** The intended use and major performance parameters (energy transmission levels and beam quality) of the OmniGuide 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

SEP 21 2006

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

Re: K062423
Trade/Device Name: Omni guide Beam Delivery 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: September 5, 2006
Received: September 6, 2006

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 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 (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 Assigned

Device Name: Omni guide Beam Delivery System

Indications For Use:

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

Prescription Use ✓ (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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



**510(k) Number** K062423