SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

K100384
(Premarket Notification [510(k)] Number)

APR 12 2010

1. Applicant

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Corresponding Official:

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2. Device Name

Device Name: CO2 Laser WaveGuide

Device trade or proprietary name: FiberLase CO2 Laser WaveGuide

Common Name: CO2 Laser WaveGuide

Classification Name: Laser Surgical Instrument, 21 CFR Section 878.4810

3. Predicate Devices

The modified CO2 Laser WaveGuide is substantially equivalent to the following device:

Device	Manufacturer	510(k) No.
CO2 Laser WaveGuide	Surgilase Inc. (acquired by Lumenis Ltd.)	K921671

4. Intended Use

The CO2 Laser WaveGuide Delivery System is intended for use in open and laparoscopic surgical procedures for ablation, vaporization, excision, incision, and coagulation of soft tissue.

5. Description of the Device

The CO2 Laser WaveGuide is a laser delivery system for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The CO2 Laser WaveGuide device is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures. The CO2 Laser WaveGuide is a hollow, semi-rigid, light-conducting tube designed to operate at wavelengths of 10.6 μm and 0.6328 μm. These wavelengths correspond to the output of the CO2 laser device and the helium-neon laser aiming beam, thereby allowing both laser radiations to be simultaneously and efficiently transmitted through the same channel. Laser energy entering the waveguide travels down the tube by multiple bounces off the inner reflective surface, and is delivered to the tissue at the distal end.

The CO2 Laser WaveGuide is compatible for use with any laser system that has a 905 SMA connector. The WaveGuide is supplied in several configurations with the dimensions specified in the following table:

Table 1 – CO2 Laser WaveGuide Dimensions

Core diameter [μm]	Outer diameters [μm]	Lengths [cm]
300	700, 800	60, 100, 150
500	900, 1040	60, 100, 150, 200
750	1200, 1400	100, 150, 200

The CO2 Laser WaveGuide is supplied with a set of eight hand pieces through which the WaveGuide may be inserted for easy handling in surgical procedures. The hand pieces are available with various features at the distal end to provide angled beam deflection

with a highly polished metal surface. The WaveGuide is also provided with cleaving and cutting tools. The WaveGuide accessories are all provided as reusable tools. The CO2 Laser WaveGuide may be used with a gas purge system providing a flow of air of 2 liters per minute and a regulator pressure of 4.5 psi. The gas purge system keeps the inner channel of the waveguide free of debris. The gas purge system is not supplied with the waveguide.

6. Performance Testing

The modified waveguide and new handpieces were bench tested to establish percent transmission using the longest length fiber optic waveguide as the worse case test scenario.

7. Technological Characteristics Compared to Predicate Device

The technological characteristics of the modified device, e.g., overall design, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the new CO2 Laser WaveGuide are substantially equivalent to the previously cleared CO2 Laser WaveGuide cited above.

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

APR 12 2010

Lumenis Ltd.
% A. Stein Regulatory Affairs Consulting Ltd.
Ms. Ahava Stein, Regulatory Consultant
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Kfar Saba 44425, Israel

Re: K100384
Trade/Device Name: CO2 Laser WaveGuide
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: March 25, 2010
Received: April 05, 2010

Dear Ms. Stein:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

SECTION 1 – INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100384

Device Name: FiberLase CO2 Laser WaveGuide

Indications for use: The FiberLase CO2 Laser WaveGuide is intended for use in surgical procedures requiring ablation, vaporization, excision, incision and coagulation of soft tissue. The FiberLase CO2 Laser WaveGuide is indicated for use in open surgical procedures such as ENT surgery and laparoscopy and endoscopic procedures. The device is limited to carbon dioxide lasers having a SMA-905 connector.

Prescription Use __√__ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use____ (Optional Format 1-2-96)

(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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100384