K050412

MAR 14 2005

VAPORMAX™ Side Firing Fiber

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information:

Trimedyne, Inc.
15091 Bake Parkway
Irvine, CA 92618
949-951-3800

Contact Person: Glenn Yeik
President and COO

Summary Date: 4 March 2005

II. Device Name

Proprietary: VAPORMAX™

Common: Laser Fiber

Classification: Accessory to Laser-Powered Instrument

III. Predicate Device

The predicate devices for the VAPORMAX Side Firing Fiber are:

- Trimedyne Side Firing Fibers cleared under 510(k)s K915223, K992230 and K022655; and
- Lumenis DUOTOME SIDELITE™ believed to have been cleared under K011703 and/or K990947.

IV. Device Description

The VAPORMAX is a single use, disposable, side firing, fiber optic energy delivery device for use with cleared Holmium:YAG lasers.

V. Intended Use

The VAPORMAX is intended for surgical use including: incision, excision, vaporization, ablation, and coagulation of soft tissue.

The VAPORMAX is indicated for use with any cleared Holmium:YAG 2.1 micrometer laser with a compatible connector for that laser's cleared indications for use.

VI. Technological Characteristics

The VAPORMAX differs from the current Trimedyne side firing devices in that it can be used at laser powers up to 100 watts, rather than 40-60 watts.

VII. Nonclinical Data

No nonclinical data were submitted in this Premarket Notification.

VIII. Clinical Data

No clinical tests were submitted in this Premarket Notification.

IX. Conclusions Drawn From Testing

The VAPORMAX performs as intended and has acceptable mechanical properties when used in accordance with its labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Trimedyne, Inc.
c/o Mr. Morten S. Christensen
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050

Re: K050412
Trade/Device Name: VaporMAX™
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: March 4, 2005
Received: March 7, 2005

Dear Mr. Christensen:

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 Mark N. Melkerson

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):

Device Name: VAPORMAX™

Indications for Use:

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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)

for Mark N Milhouse

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

510(k) Number K050412