Attachment 4 K992230

510(k) Summary of Safety and Effectiveness Information

Trimedyne® OmniTip™ Side Firing Switchable Tips with Suction/Irrigation

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.
P.O. Box 57001
Irvine, CA 92619-7001
(949) 559-5300
(949) 559-1330

Contact person: Susan H. Gamble
Vice President, Regulatory Affairs and Quality

Summary Date: July 1, 1999

II. Device Name

Proprietary: OmniTip™ Side Firing Switchable Tip with Suction/Irrigation

Common: Laser Fiber

Classification: Accessories to Laser-Powered Instrument (unclassified)

III. Predicate Device

The predicate devices are the Trimedyne OmniTip™ Switchable Tips and Tapertip™ Holmium Arthroscopic Handpieces.

IV. Device Description

The OmniTip Side Firing Switchable Tip with Suction/Irrigation is a fiber optic energy delivery device consisting of a near-contact laser fiber enclosed in a needle assembly of a capillary tube and an external stainless steel shaft. The device is attached to the Omni Multiuse Handpiece through a quick-connect mechanism. A luer connector assembly installed at the proximal end of the device connects the suction/irrigation channel to a pump via an external line.

V. Intended Use

This device is intended for use with any Holmium laser (with a compatible connector) for its cleared applications.

VI. Technological Characteristics

The device differs from the predicate devices due mainly only to the incorporation of suction/irrigation channel and minor configuration changes.

VII. Nonclinical Tests

The device was subjected to a series of tests, including mechanical, biological, and performance studies.

VIII. Clinical Tests

The device was subjected to a simulated clinical testing using heart tissue. A physician's feedback is also used to validate the use of the device in a clinical setting.

IX. Conclusions Drawn from Testing

The device is biocompatible, performs as intended, and has acceptable mechanical properties when used according to its labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Ms. Susan H. Gamble
Vice President, Regulatory Affairs and Quality
Trimedyne, Inc.
2801 Barranca Road
P.O. Box 57001
Irvine, California 92619

Re: K992230
Trade Name: OmniTip™ Side Firing Switchable Tip with Suction/Irrigation
Regulatory Class: II
Product Code: GEX, GCX, and GBX
Dated: July 1, 1999
Received: July 2, 1999

Dear Ms. Gamble:

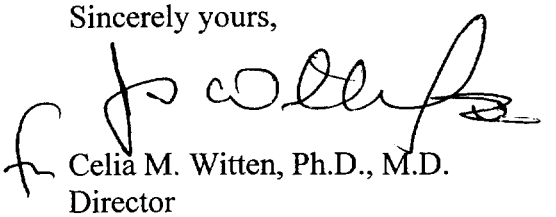
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number K992230

Device Name OmniTip™ Side Firing Switchable Tip with Suction/Irrigation

Indications for Use The OmniTip™ Side Firing Switchable Tip with Suction/Irrigation is intended for use with any pulsed Holmium:YAG 2.1 micrometer laser with a compatible connector for incision, excision, ablation, vaporization, and coagulation.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Sign Off.

(AN) Number K992230