

FEB - 3 1998

Summary of 510(k) Safety and Effectiveness Information
Responsible Holmium Bare Fibers

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
714/559-5300
714/559-1330
- Contact Person:** Susan H. Gamble
Vice President, Regulatory Affairs & Quality Assurance
- Summary Date:** December 22, 1997
- II. Device Name**
- Proprietary:** Responsible Holmium Bare Fibers
- Common:** Laser Fiber
- Classification:** Accessories to Laser-Powered Instruments
- III. Predicate Device**
- The predicate devices are the Trimedyne Disposable Holmium Bare Fibers.
- IV. Device Description**
- The Responsible Holmium Bare Fibers are reusable fiberoptic energy delivery devices. These devices consist of an optical fiber which may or may not be contained in a catheter tube, cannula, needle, handpiece or handle. The fibers range from 50 to 1000 microns core diameter and will be offered with various distal tip configurations.
- V. Intended Use**
- These devices are intended for use with any pulsed Holmium:YAG 2.1 micrometer laser (with compatible connector) for incision, excision, resection, ablation, vaporization, coagulation and hemostasis.
- VI. Technological Characteristics**
- The devices differ from their predicate devices due only to the incorporation of minor materials and configuration changes which allow for steam and EtO sterilization/reuse.
- VII. Nonclinical Tests**
- No nonclinical test data were submitted in this Premarket Notification.
- VIII. Clinical Tests**
- No clinical tests were submitted in this Premarket Notification.
- IX. Conclusions Drawn from Testing**
- Not applicable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susan H. Gamble
Vice President, Regulatory Affairs & Quality Assurance
Trimedyne, Incorporated
P.O. Box 57001
Irvine, California 92619-7001

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Re: K973172
Trade Name: Resposable Holmium Bare Fibers
Regulatory Class: II
Product Code: GEX
Dated: December 22, 1997
Received: December 23, 1997

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.

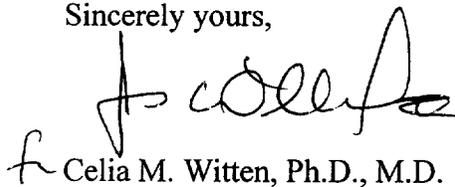
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. ~~A substantially equivalent determination assumes compliance with the~~ current Good Manufacturing Practice requirements, 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

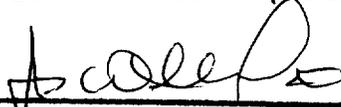
510(k) Number (if known): K973172

Device Name: Resposable Holmium Bare Fibers

Indications for Use: Incision, excision, resection, ablation, vaporization, coagulation and hemostasis.

(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 General Restorative Devices
510(k) Number

K973172

Prescription Use

OR

Over-the-Counter Use