SEP 23 2002 K 013974

510(k) Summary of Safety and Effectiveness Information
Trimedyne Holmium Laser Systems

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

Contact person: Laurie Cartwright
Manager, Regulatory Affairs

Or

Glenn Yeik
Executive Vice President

Summary Date: June 24, 2002

II. Device Name

Proprietary: Trimedyne Holmium Laser System, including:

- Trimedyne OmniPulse™ Holmium Laser System (Model 1210)
- Trimedyne OmniPulse MAX™ Holmium Laser System (Model 1210-VHP)
- Trimedyne OmniPulse Jr.™ Holmium Laser System (Model 1230-30)
- Model 1500-A Holmium Laser System

Common: Holmium:Yttrium Aluminum Garnet (Holmium:YAG) Laser

Classification: Laser-Powered Instrument

III. Predicate Device

Standard surgical instruments, such as knives and forceps.

IV. Device Description

The Trimedyne Holmium Laser System is a medical grade, Class IV, pulsed, solid state Holmium:YAG laser system designed to deliver pulsed infrared laser energy with a wavelength of 2.1 μm and 350 microseconds pulsewidth. Menu-driven control options allow the users to select pulse repetition rate, output energy, and lasing duration.

V. Intended Use

The Trimedyne Holmium:YAG Laser System is intended for incision, excision, resection, ablation, vaporization, coagulation, and hemostasis in multispecialty applications. The applications addressed in this premarket notification include percutaneous cervical, lumbar, and thoracic disc decompression/discectomy.

VI. Technological Characteristics

The laser system is a Holmium:YAG laser that emits light at a wavelength of 2.1 μm (near infrared) and a pulsewidth of 350 microseconds. The laser has the capability of attaining a maximum output of 100 watts of power.

VII. Animal Data and Human Clinical Data

Animal data and human clinical data from published literature were included in this premarket notification to demonstrate that the Trimedyne Holmium Laser Systems are safe and effective for the specified indications.

VIII. Conclusion

The Trimedyne Holmium:YAG Laser System is substantially equivalent to the predicate device described in this premarket notification. Furthermore, the non-clinical and clinical data submitted demonstrated the safety and effectiveness of the device for the proposed applications. Therefore, upon clearance of this submission, the Trimedyne Holmium:YAG Laser System will be marketed for the proposed expanded indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Ms. Laurie Cartwright
Manager, Regulatory Affairs
Trimedyne, Inc.
15091 Bake Parkway
Irvine, CA 92618

Re: K013974
Trade/Device Name: Trimedyne Holmium Laser Systems:
OmniPulse™ Holmium Laser System, Model 1210
OmniPulse MAX™ Holmium Laser System, Model 1210-VHP
OmniPulse Jr.™ Holmium Laser System, Model 1230-30
Model 1500-A Holmium Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: June 24, 2002
Received: June 25, 2002

Dear Ms. Cartwright:

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.

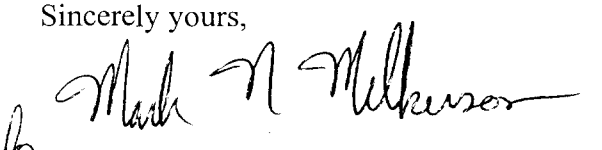
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Indications Page

Note: This indications page includes only the indications statement affected by this premarket notification submission.

510(k) Number (if known): K013974

Device Name: Trimedyne Holmium Laser Systems, including:

- OmniPulse™ Holmium Laser System, Model 1210
- OmniPulse MAX™ Holmium Laser System, Model 1210-VHP
- OmniPulse Jr.™ Holmium Laser System, Model 1230-30
- Model 1500-A Holmium Laser System

Indications for Use:

Incision, excision, resection, ablation, coagulation, hemostasis, and vaporization, with or without an endoscope, in the following indications:

- *Percutaneous Lumbar Disc Decompression/Discectomy* in soft, cartilaginous, and bony tissue, including:
  - foraminoplasty
- *Percutaneous Cervical Disc Decompression/Discectomy* in soft tissue, in patients with:
  - Uncomplicated ruptured or herniated discs
  - Neck pain with radiation down the arm
  - Symptoms and signs of sensory loss, tingling, numbness, muscle weakness, and/or decreased deep tendon reflexes
  - MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms
  - Positive electromyography and/or nerve conduction studies
  - No improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)
- *Percutaneous Thoracic Disc Decompression/Discectomy* in soft tissue, in patients with:
  - Uncomplicated ruptured or herniated discs
  - Thoracic and intercostal intractable pain
  - Paresthesias at levels appropriate to the herniated discs visualized on MRI and CT-myelography
  - MRI, CT, myelogram, or discogram findings of disc herniation consistent with patient signs and symptoms
  - No improvement after 12 weeks of conservative therapy (i.e., physical therapy, traction, bed rest, exercises, and medication)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A. Milhern

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

510(k) Number K013974

Prescription Use ✓ OR Over-the-Counter Use _____