

JUN 28 1999

**510(k) Summary Statement for the
Acme Medical Nd:YAG Aesthetic Laser**

K991234

I. General Information

Submitter: Acme Medical, Inc.
1181 Chess Drive, Suite B
Foster City, CA 94404

Contact Person: Michael Levernier

Summary Preparation Date: 09 April 1999

II. Names

Device Names: Acme Medical Nd:YAG Aesthetic Laser

Primary Classification Name: Laser Powered Surgical Instrument for use in Plastic Surgery and Dermatology in accordance with 21 CFR 879-4810. 79-GEX

III. Predicate Devices

The product specifications, functionality, indications for use, and treatment parameters of the Acme Medical Aesthetic Nd:YAG Laser are the same or very similar to the following legally marketed lasers:

- ◆ ESC VascuLight DL (K980537)
- ◆ HMG VeinLase (K981952)

IV. Product Description

The Acme Medical Nd:YAG Aesthetic Laser is a long pulsed, solid-state infrared laser. It is intended to deliver laser energy for use in surgical applications requiring coagulation and hemostasis of vascular lesions. The Aesthetic Nd:YAG Laser produces a beam of infrared light at a wavelength of 1064nm. The system consists of:

- a laser console;
- internal computer;
- control and display panel;
- permanently attached fiber optic delivery system;
- handswitch with the option of a footswitch; and
- fiber optic coupled handpiece and tip with cooling capability.

V. Indications for Use

The Acme Medical Aesthetic Nd:YAG Laser is intended for dermatologic use. The 1064nm wavelength, long pulse duration, and large spot size of the Acme Medical Aesthetic Nd:YAG Laser allows for effective coagulation and hemostasis of vascular lesions. The laser system consists of a laser console and a delivery handpiece. The delivery handpiece is placed in contact with the target via a contact tip that is capable of cooling the epidermis. Clinical use of the device is indicated for clinical practitioners in plastic surgery and dermatology who have been technically trained on the use of the Acme Medical Aesthetic Nd:YAG Laser.

VI. Rationale for Substantial Equivalence

The Acme Medical Aesthetic Nd:YAG Laser shares the same indications for use, similar design features (including wavelength, active medium, cooling system, and controls), similar functional features (including pulse duration, and fluence), and similar treatment parameters of other marketed long pulsed Nd:YAG laser systems (as opposed to the Q-switched lasers). Therefore, the Acme Medical Aesthetic Nd:YAG Laser is substantially equivalent to the HGM VeinLase (K981952) and the ESC Vasculight DL (K980537).

VII. Safety and Effectiveness Information

No performance data was submitted in conjunction with this Premarket Notification submission. The determination of substantial equivalence was based upon the comparison of the technical and functional characteristics between the Acme Medical Aesthetic Nd:YAG Laser and the predicate lasers and delivery systems. For this reason, performance data is not required.

VIII. Conclusion

The Acme Medical Aesthetic Nd:YAG Laser system and delivery device was found to be substantially equivalent to similar currently marketed surgical laser devices for dermatologic applications. The Acme Medical Aesthetic Nd:YAG Laser shares identical indications for use, similar product specifications, and similar functional features as the currently marketed long pulsed, 1064nm wavelength Nd:YAG surgical lasers and their delivery devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Michael Levernier
Director, Regulatory/Clinical Affairs
and Marketing
Acme Medical, Inc.
1181 Chess Drive, Suite B
Foster City, California 94404

Re: K991234
Trade Name: Acme Medical Aesthetic Nd:YAG Laser
Regulatory Class: II
Product Code: GEX
Dated: April 8, 1999
Received: April 12, 1999

Dear Mr. Levernier:

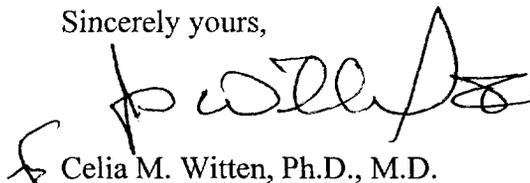
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,

A handwritten signature in black ink, appearing to read "C. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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): K991234

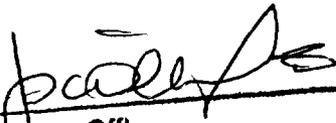
Device Name: Acme Medical Aesthetic Nd:YAG Laser

Indications for Use:

For coagulation and hemostasis of vascular lesions.

(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 K991234
510(k) Number _____

(Optional Format 3-10-98)