3/22/99

K990725

Summary of Safety and Effectiveness

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact:

Daniel Hoefer
American Laser Medical, Inc.
1832 South 3850 West
Salt Lake City, UT 84104
(801) 972 1311, FAX (801) 972 5251

Name of Device:

Trade Name: Nuvolase 532 Laser System for Opthalmology

Common Name: Ophthalmic Laser Photocoagulator

Classification Name: Ophthalmic Laser (per 21 CFR 886.4930)

Predicate Devices:

The Nuvolase 532 Laser System for Opthalmology has been modified from the American Laser Medical, Inc. Nuvolase 660 Laser System for Ophthalmology, K972561.

Description of Device:

The Nuvolase 532 Laser System for Ophthalmology is a continuous-wave frequency-doubled diode-pumped Nd:YAG laser system. Treatement beam power output for the system is 50 milliwatts to 1.5 watts at a wavelength of 532 nm. Depending on the delivery device efficiency, the maximum power level may be as much as 2.0 Watts CW. The aiming beam is provided by a red diode laser operating at 670 nm. Exposure durations for the Nuvolase 532 Laser System for Ophthalmology (in seconds) are 0.05, 0.1, 0.25, 0.5, 1.0, and continuous. Delivery of the beam occurs via fiber optic and laser slit lamp.

Intended Use:

The Nuvolase 532 Laser System for Ophthalmology is intended for use in retinal and macular photocoagulation and trabeculoplasty.

Technological Characteristics/Device Comparison:

The Nuvolase 532 Laser Sysem is a modification of the Nuvolase 660 Laser System for Ophthalmology, already in legal commercial distribution. Each of the systems optically pumps an Nd:YAG crystal using 808 nm diodes to produce laser light at 1064 nm. This light passes through a second crystal which exhibits a non-linear optical response, re-emitting the laser energy at the first harmonic of the 1064 line, 532 nm greeen. The continuous wave beam is then shuttered electro-mechanically to produce the desired exposure durations. Each device is intended for retinal and macular photocoagulation and trabeculoplasty. The delivery system is the same in each case.

Conclusion:

The device modification does not affect the indications for use, materials, method of manufacture, or technology of the legally marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 22 1999

Mr. Daniel Hoefer
Regulatory Affairs
American Laser Medical, Inc.
1832 South 3850 West
Salt Lake City, Utah 84104

Re: K990725
Trade Name: Nuvolase 532 Laser System For Ophthalmology
Regulatory Class: II
Product Code: GEX
Dated: March 4, 1999
Received: March 5, 1999

Dear Mr. Hoefer:

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

510(k) Number (if known): 990725

Device Name: NUVOLASE 532 LASER SYSTEM FOR OPHTHALMOLOGY

Indications For Use:

1. RETINAL AND MACULAR PHOTOCOAGULATION
2. TRABECULOPLASTY

(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 K990725

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)