

3/22/99

Nuvolase 532 Laser System for Ophthalmology
American Laser Medical, Inc.
March 5, 1999

K990780

Summary of Safety and Effectiveness

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact:

Daniel Hoefler
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 Cutaneous Laser System

Common Name: Dermatology Laser

Classification Name: Laser Instrument, Surgical, powered (per 21 CFR 878.4810)

Predicate Devices:

The Nuvolase 532 Laser System for Ophthalmology has been modified from the American Laser Medical, Inc. Nuvolase 660 Laser System, K970667.

Description of Device:

The Nuvolase 532 Cutaneous Laser System is a continuous-wave frequency-doubled diode-pumped Nd:YAG laser system. Treatment beam power output for the system is 50 milliwatts to 1.5 watts at a wavelength of 532 nm. The maximum power level to tissue is 2.5 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 handpiece.

Intended Use:

The Nuvolase 532 Laser System for Ophthalmology is intended for use in the treatment of vascular lesions of the skin, including capillary hemangioma (port wine stain), strawberry hemangioma, telangiectasia, and rosacea. It is also intended for pigmented lesions including freckles, age spots, café-au-lait, and lentigo.

Technological Characteristics/Device Comparison:

The Nuvolase 532 Laser System is a modification of the Nuvolase 660 Laser System, 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 green. The continuous wave beam is then shuttered electro-mechanically to produce the desired exposure durations. Each device is intended for treatment of vascular and pigmented lesions of the skin. The delivery system is equivalent 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 22 1999

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

Re: K990780
Trade Name: Nuvolase 532 Cutaneous Laser System
Regulatory Class: II
Product Code: GEX
Dated: March 5, 1999
Received: March 9, 1999

Dear Mr. Hoefler:

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.

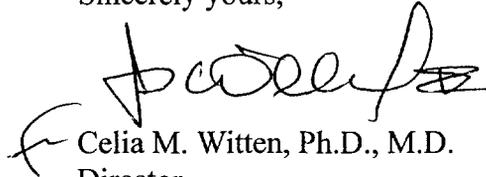
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 – Mr. Daniel Hoefler

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 'Celia M. Witten', with a stylized flourish at the end.

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): K990780

Device Name: NUVOLASE 532 CUTANEOUS LASER SYSTEM

Indications For Use:

VASCULAR LESIONS:

1. CAPILLARY HEMANGIOMA (PORT-WINE STAIN)
2. STRAWBERRY HEMANGIOMA
3. TELANGIECTASIA
4. ROSACEA

PIGMENTED LESIONS:

1. FRECKLES
2. AGE SPOTS
3. CAFE-AU-LAIT
4. LENTIGO

(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

K990780

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)