

OCT - 6 1997

Nuvo-Lase 660 Laser System
American Laser Medical, Inc.
July 8, 1997

510(k) Summary

K972561

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contact:

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

Name of Device:

Trade Name: NuvoLase 660 Laser System

Common Name: Ophthalmic Laser Photocoagulator

Classification name: Ophthalmic Laser (per 21 CFR 886.4930)

Product Code: 86 HQF

Predicate Devices:

The NuvoLase 660 is substantially equivalent to the following legally marketed devices: The Prima 532 marketed by Nidek, Inc., and the Oculight GL marketed by IRIS Medical Instruments.

Description of Device:

The NuvoLase Model 660 is a continuous wave frequency-doubled diode-pumped Nd:YAG laser system.

Description of Device (cont.):

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Treatment beam power output for the NuvoLase 660 laser is adjustable to a maximum of 2.0 Watts continuous wave at 532 nm. The aiming beam is provided by a red diode laser operating at 670 nm. Exposure times for the NuvoLase 660 Laser System (in seconds) are 0.02, 0.05, 0.1, 0.25, 0.5, 1.0, and continuous. Delivery of the beam occurs via Rodenstock RO 5000 LS laser slit lamp, connected to the laser by fiber optic.

Intended Use:

The NuvoLase 660 Laser System is intended for use in retinal and macular photocoagulation and trabeculoplasty.

Technological Characteristics/Device Comparison:

The NuvoLase 660 Laser System is substantially equivalent to the Nidek Prima 532 and the IRIS Oculight GL Laser Photocoagulator already in commercial distribution. Each of these systems optically pumps an Nd:YAG crystal (NuvoLase 660 and Oculight GL using 808 nm diodes, Prima 532 using flashlamps) 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 nm line, 532 nm green. The continuous wave beam is then shuttered either mechanically or electro-optically to produce the desired exposure durations.

Each of these devices is intended for use in retinal photocoagulation, iridotomy, and trabeculoplasty. Each is a 532 nm true continuous wave device, generated by a frequency doubled diode pumped Nd:YAG crystal. Laser energy is delivered by equivalent delivery devices in each case.

Conclusion:

The NuvoLase 660 Laser System is substantially equivalent to the Prima 532 marketed by Nidek, Inc. and the Oculight GL marketed by Iris Medical Instruments, already in legal commercial distribution. The materials, design, intended use, method of manufacture, warnings, cautions, and precautions are all substantially the same.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT - 6 1997

Re: K972561
Trade Name: NuvoLase 660 Laser System
Regulatory Class: II
Product Code: GEX
Dated: July 8, 1997
Received: July 9, 1997

Dear Mr. Hoefler:

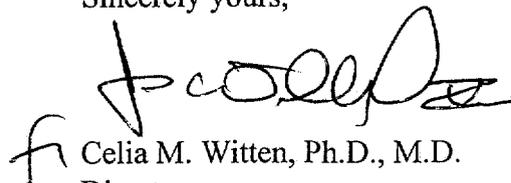
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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

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): K972561

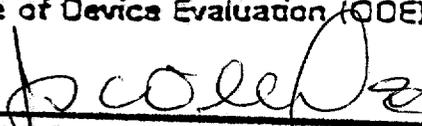
Device Name: NuvoLase 660 Laser System

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

K972561

Prescription Use
(Per 21 CFR 801.109)

OR

Over The-Counter Use

(Optional Format 1-2-56)