

K974900

FEB 27 1998

510(K) Summary

Submitter: Cynosure, Inc.
10 Elizabeth Drive
Chelmsford, MA 01824

Contact: George Cho
Senior Vice President of Medical Technology

Date Summary Prepared: December 24, 1997

Device Trade Name: PhotoGenica 532 Laser

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.48

Equivalent Device: American Medical Laser Nuvo-Lase 660 Laser

Device Description: The PhotoGenica 532 Laser is a CW, frequency-doubled Nd:YAG laser system with a wavelength at 532 nm. The treatment beam output for the PhotoGenica 532 is 4 watts CW at 532 nm.

The aiming beam is provided by 5 mW, 670 nm diode laser. Exposure times for the PhotoGenica 532 (in seconds) are 0.02, 0.05, 0.1, 0.25, 0.5, 1.0 and continuous.

Laser activation is by a footswitch. Overall weight of the unit is 25 lb (11 kg).

Electrical power requirement is 120/230 VAC \pm 10%, 5/3 Amps, 50-60 Hz. The system is air-cooled by fans.

Accessories available for use with the PhotoGenica 532 include 0.2, 0.5, 0.7, 1.0 and 1.5 mm (spot diameter) handpieces.

Intended Use: The PhotoGenica 532 Laser system is indicated for the treatment of vascular and pigmented lesions of the skin.

Comparison: The PhotoGenica 532 Laser is substantially equivalent to the Nuvo-Lase 660 Laser in terms of treatment wavelength, pulse duration, power, and biological effects.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The PhotoGenica 532 Laser is another safe and effective way to treat vascular or pigmented lesions of the skin..

Additional Information: None requested at this time



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. George Cho
Senior Vice President
Cynosure, Incorporated
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K974900
Trade Name: Cynosure PhotoGenica 532 Laser
Regulatory Class: II
Product Code: GEX
Dated: December 24, 1997
Received: December 30, 1997

Dear Mr. Cho:

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.

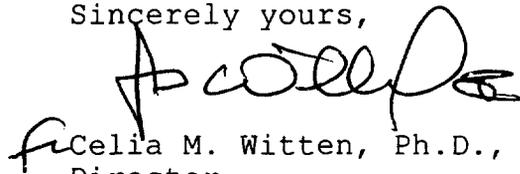
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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.

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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): K974900

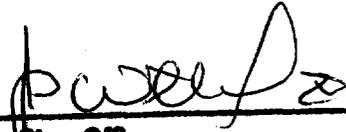
Device Name: Cynosure PhotoGenica 532 Laser

Indications For Use:

The PhotoGenica 532 laser is indicated for the treatment of benign cutaneous vascular and pigmented 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
510(k) Number K974900

Prescription Use X

OR

Over-The-Counter Use _____