FEB 13 2006

510(K) Summary

K053608

Submitter:	Cynosure, Inc. 5 Carlisle Road Westford, MA 01886
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	December 21, 2005
Device Trade Name:	Cynosure PhotoGenica V-Star Laser
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.4810
Equivalent Device:	Cynosure PhotoGenica VLS-Star Laser
Device Description:	The Cynosure PhotoGenica V-Star laser is a pulse dye laser, having an organic dye as a lasing medium. Laser activation is by footswitch or finger switch. Overall weight of the laser is 285lbs, and the size is 44"x19"x24" (HxWxD). Electrical requirement is 220 VAC, 30A, 50-60 Hz, single phase.
Intended Use:	The Cynosure PhotoGenica V-Star Laser is indicated for benign vascular and vascular dependent lesion removal, and the treatment of benign epidermal pigmented lesions.
Comparison:	The Cynosure PhotoGenica V-Star Laser has the same indications for use, the same principle of operation, and similar wavelengths and pulse energy range as the predicate device(s).
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Cynosure PhotoGenica V-Star Laser is a safe and effective device for the indications specified.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. George Cho
Senior Vice President
Medical Technology
Cynosure, Inc.
5 Carlisle Road
Westford, Massachusetts 01886

Re: K053608
Trade/Device Name: Cynosure PhotoGenica V-Star Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 22, 2005
Received: December 27, 2005

Dear Mr. Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Brenner
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K053608

Device Name: Cynosure PhotoGenica V-Star Laser

Indications For Use:

General Surgery: Photocoagulation of benign cutaneous vascular and vascular dependent lesions and benign cutaneous lesions.
Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesions, such as facial
and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and psoriasis and the treatment of wrinkles. Treatment of Benign Epidermal Pigmented Lesions.
Treatment of Inflammatory Acne Vulgaris
Gynecology: Photocoagulation of benign cutaneous lesions and benign vascular lesions in
gynecology.
Podiatry: Treatment of benign cutaneous lesions, such as warts.

Prescriptive Use X OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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