Study Summary

K973499

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	September 11, 1997
Device Trade Name:	PhotoGenica Er Laser
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	Continuum Biomedical CB Erbium / 2.94™ Er:YAG Laser
Device Description:	The PhotoGenica Er Laser consists of three interconnected sections: the power supply, the water cooling system and the optical bench. At 20 pulses per second and a pulse energy of 2 Joules, the average power from the laser is 20 watts.
Intended Use:	Skin resurfacing and for the incision, excision, ablation or vaporization of soft bodily tissues
Comparison:	The PhotoGenica Er Laser is substantially equivalent to the Continuum Biomedical CB Erbium / 2.94™ Er:YAG Laser in terms of treatment wavelength, pulse duration, pulse energy, and biological effects.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The PhotoGenica Er is another safe and effective laser for skin resurfacing and for the incision, excision, ablation or vaporization of soft bodily tissues.
Additional Information:	None requested at this time

NOV 13 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

NOV 1 3 1997

Re: K973498
Trade Name: CYNOSURE PhotoGenica ER Laser
Regulatory Class: II
Product Code: GEX
Dated: September 12, 1997
Received: September 15, 1997

Dear Mr. Cho:

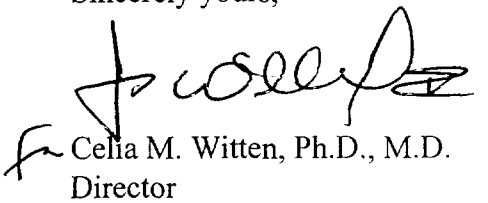
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K973498

Device Name: Cynosure PhotoGenica Er Laser

Indications For Use:

The PhotoGenica Er laser is used for skin resurfacing and for the incision, excision, ablation or vaporization of soft bodily tissues.

Typical applications include dermatology, plastic surgery, urology, gastroenterology, neurosurgery, gynecology, arthroscopy, general surgery, ENT and ophthalmology.

(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 K973498

Prescription Use X OR Over-The-Counter Use_____

(Optional Format 1-2-96)