

JUN 27 2005

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**510(K) Summary**

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

Contact: George Cho  
Senior Vice President of Medical Technology

Date Summary Prepared: March 25, 2005

Device Trade Name: Cynergy Multiplex Laser

Common Name: Medical Laser System

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

Equivalent Device: Cynosure Cynergy laser

Device Description: The Cynergy Multiplex laser is user selectable, multi wavelength laser, having both an organic dye and an Nd:YAG rod lasing medium. It is a pulsed dye laser with wavelengths of 585, 590, 595, 600 nm and an Nd:YAG laser with a wavelength of 1,064 nm. It is capable of delivering one wavelength pulse or mixing of two wavelengths pulse.

Laser activation is by footswitch. Overall weight of the laser is 285lbs, and the size is 44"x19"x24" (HxWxD).

Electrical requirement is 110 VAC or 220 VAC, 20A, 50-60 Hz, single phase.

Intended Use: The Cynergy Multiplex is indicated for treatment of vascular lesions, pigmented lesions, tattoos, wrinkles and hair removal.

Comparison: The Cynergy Multiplex laser is substantially equivalent to the predicate laser with the same principle of operation, and similar wavelengths and fluence ranges as the predicate devices.

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Cynergy Multiplex laser is another safe and effective device for treating vascular lesions, pigmented lesions, tattoos, wrinkles and hair removal.

Additional Information: none



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 27 2005

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

Re: K050779

Trade/Device Name: Cynosure Cynergy 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: March 25, 2005

Received: March 28, 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.

Page 2 – Mr. George Cho

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" (21CFR 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,



*for* Miriam C. Provost, Ph.D.  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Name of Manufacturer:** Cynosure, Inc.

**Laser Model Name and Number:** CYNERGY MULTIPLEX LASER for surgery and dermatology.

**Laser Type:** (Circle all that apply)

Alexandrite, Argon, CO<sub>2</sub>, Copper-Vapor, Diode, Dye, Nd:YAG, Erbium, Hol:YAG, Krypton, Ruby, KTP/532, Excimer, HENE, Accessory, Other \_\_\_\_\_

**Indications in this application:** Treatment of vascular lesions, pigmented lesions, tattoos, wrinkles and hair removal when a single wavelength pulse is delivered. In the multiplex mode, *only* benign vascular and vascular dependent lesion removals are indicated.

**FDA Document Control Number:** K050779/A1

**FDA Product Code:** 79GEX

**Reviewer Computer Initials:** ABC

**Date of Clearance Letter:** 6/22/05

**Basis of Approval:** (Circle all that apply)

Predicate Device (PD),  Clinical Data (CD),  Animal Data (AD),  Specifications (SPECS),  Bench Test Data (BTD),  Historical Information (HI), Other \_\_\_\_\_

**Description of Laser:** The system is a user selectable, multi-wavelength laser including both an organic dye and a Nd:YAG rod lasing medium. It is capable of delivering one wavelength pulse or a combination of two wavelength pulses (PDL followed by Nd:YAG).

**Operation Modes:** (Circle all that apply)

CW,  Pulsed,  Q-Switched,  Mode Locked,  Contact,  Free Beam, Other \_\_\_\_\_

**Wavelength in Nanometers:** 1064; 585, 590, 595 & 600; capable of mixing two wavelengths.

**Power/Energy Range (Watts/Joules):** max 25 J/cm<sup>2</sup> (PDL); 300 J/cm<sup>2</sup> (Nd:YAG)

**Pulse Width:** 0.5-40 ms (PDL); 0.5-300 ms (Nd:YAG)

**Repetition Rate:** Single: 1-2 Hz (PDL); 1-10 Hz (Nd:YAG)

**Delivery System:** Single optical fiber (lens-coupled quartz), one for each head, and hand pieces with spot sizes ranging from 4.8-12.3 mm (PDL) or 2.8-15.3 mm (Nd:YAG)

**Comments:** The delay times between two pulses can range from 20-2000 ms. In the absence of new clinical data for multiplex applications, *only* removal of benign vascular and vascular-dependent lesions is indicated for the multiplex mode.

510(k) Number (if known): K050779/A1

Device Name: Cynosure Cynergy Laser

Indications For Use:

585 – 600nm: The Cynergy laser is indicated for benign vascular and vascular dependant lesions removal.

1,064nm: The Cynergy laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lakes, leg veins, spider veins, and poikiloderma of civatte and treatment of benign cutaneous lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), café au lait manules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

Additionally, the laser is intended for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of psuedofolliculitis barbae (PFB).

585 – 600nm with 1,064nm Wavelength Multiplex Mode: The wavelength multiplex mode is intended for benign vascular and vascular dependant lesions removal.

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)

  
\_\_\_\_\_  
(Division Signatory)  
Division of General Electromagnetic  
and Neurological Devices

510(k) Number: K050779