

K080121

**510(K) Summary**

Submitter: Cynosure, Inc.  
5 Carlisle Road  
Westford, MA 01886

Contact: George Cho  
Senior Vice President of Medical Technology

Date Summary Prepared: January 16, 2008

Device Trade Name: Cynosure Smartlipo Multiwavelength Laser

Common Name: Medical Laser System

Classification Name: Instrument, surgical, powered, laser  
79-GEX  
21 CFR 878.4810

Equivalent Device: The Cynosure YAG Family laser

Device Description: The Cynosure Smartlipo Multiwavelength laser is a Nd:YAG laser, having a ND:YAG crystal rod as a lasing medium. It is a laser with a wavelength of 1064 nm and 1320 nm.

Laser activation is by footswitch. Overall weight of the laser is 285lbs, and the size is 41"x18"x32" (HxWxD).

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

Intended Use: The SmartLipo Multiwavelength Laser is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. All soft tissue is included, such as skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The SmartLipo is further indicated for laser assisted lipolysis.

Comparison: The Cynosure Smartlipo Multiwavelength Laser has the equivalent indications for use, the same principle of operation, and the same laser parameters as the predicate device(s).

Nonclinical Performance Data: none

Clinical Performance Data: none

Conclusion: The Cynosure Smartlipo Mutliwavelength Laser is a safe and effective device for the 'indications for use' specified.

Additional Information: none

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K080121

Trade/Device Name: Cynosure Smartlipo Multiwavelength Laser  
Regulatory Number: 21 CFR 878.4810  
Regulatory Name: Laser surgical instrument for use in general and plastic surgery and  
in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: January 16, 2008  
Received: January 17, 2008

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

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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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: Cynosure Smartlipo Multiwavelength Laser

Indications For Use:

The Cynosure Smartlipo Multiwavelength Laser is intended for the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue. Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands. The Cynosure Smartlipo Multiwavelength Laser is further indicated for laser assisted lipolysis.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number 1080121