K102541

JAN 26 2012

510(K) Summary

Submitter:	Cynosure, Inc. 5 Carlisle Road Westford, MA 01886
Contact:	Irina Kulinets Vice President of Regulatory Affairs and Quality Systems
Date Summary Prepared:	October 3, 2012
Device Trade Name:	Cynosure Cellulaze Laser
Common Name:	Medical Laser System
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology 21 CFR 878.4810
Equivalent Device:	SmartLipo Multiwavelength with 1440nm Wavelength, K091537
Device Description:	The Cynosure Cellulaze laser is an Nd:YAG laser, with a wavelength of 1440nm. The energy delivering laser optical fiber is housed within a cannula and is combined with the temperature monitoring guide functioning as a safety feature that prevents the laser from generating temperature above the safety range.
Intended Use:	The Cellulaze Laser is intended for the short term improvement in the appearance of cellulite.
Comparison:	The Cynosure Cellulaze Laser has similar intended use, the same principle of operation, and the same performance specifications as the predicate device. Additionally the same temperature monitoring device as in the predicate device is utilized to ensure temperature within the specified range. The use of the temperature monitoring device to control site temperature is identical to how this same laser system is used for the prior clearance of fat lipolysis, both predicate device and Cellulaze rely on control temperature to produce fat melting without causing adverse effects associated with higher temperatures.
Nonclinical Performance Data:	None
Clinical Performance Data:	Data from two clinical studies enrolling a total of 106 subjects were provided to support safety and efficacy of the device.

The clinical dataset used to support the efficacy of the specific indication for use was collected in a clinical study that enrolled 57 subjects. The company provided data from two co-primary endpoints, ability of blinded evaluators to correctly identify baseline photographs and evaluation of improvement in the appearance of cellulite by blinded evaluator scoring of pre and post treatment photographs. The blinded evaluation was made using 3 month post-treatment photographs.

Success for identification of baseline photographs was at least 80% of the photographs being correctly identified. For this endpoint the range for the 3 evaluators was 91-95% which exceeded the predetermine success criteria.

For the endpoint that evaluated improvement, success was established as 80% of the sites showing a pre-specified improvement on a validated scale. Blinded evaluation of this endpoint showed 91% of the sites meeting this requirement.

A total of 103 subjects were evaluated for safety. Adverse events reported in the two studies included pain, redness, swelling, purpura, itching, numbness, blistering, hardness, seroma, and necrosis. These types of adverse events are common to this type of procedure. All of these events did resolve without need for medical intervention.

Conclusion:

The similarity in technical characteristics combined with the clinical safety and effectiveness data demonstrate that the Cynosure Cellulaze Laser is substantially equivalent to the predicate device for the indication for use specified.

Additional Information:

None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

Re: K102541
Trade/Device Name: Cynosure Cellulaze Laser and Cellulaze Delivery Kit
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OYW
Dated: January 20, 2012
Received: January 23, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go.to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

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

Enclosure

Indications For Use

510(k) Number (if known): K102541

Device Name: Cynosure Cellulaze Laser

Indications For Use:

The Cynosure Cellulaze Laser is intended for the short term improvement in the appearance of cellulite.

Prescriptive Use _X_ (21 CFR 801 Subpart D)

OR, Over-The-Counter Use _____ (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 Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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