K 121127

MAY 13 2012

510(k) Summary

510(K) Owner:

CYNOSURE, INC.
5 Carlisle Road
Westford, MA 01886
Telephone: 978-256-4200
Fax: 978 256 6556
Owner/Operator Number: 9006419

Contact:

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Submitter:

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Manufacturer:

CYNOSURE, INC.
5 Carlisle Road
Westford, MA 01886
Telephone: 978-256-4200
Fax: 978-256-4200
Establishment Registration Number: 1222993

Date Prepared: 12 April 2012

Trade name: SideLaze800™, laser beam delivery accessory for Cynosure 1440nm wavelength lasers

Common name: Powered Laser Surgical Instrument (Laser for Surgery and Dermatology)

Classification name: 21 CFR 878.4810

Product Code(s): GEX (Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology)

Classification: Class II

Predicate Devices (Claiming Substantial Equivalence):

Cynosure Multiwavelength Laser with 1440nm Wavelength
K091537

Cynosure Cellulaze Laser and Cellulaze Delivery Kit
K102541

Twister™ Side-Firing Optic Delivery System
K112987

Summary Description of the Device:

SideLaze800™ is an optional side-firing fiber optic accessory to the currently cleared Cynosure Lasers with 1440nm wavelength. The addition of the Cynosure SideLaze800™ option to the cleared laser devices is intended to offer physicians a convenient accessory within cleared indications for use.

Intended Use / Indications for Use:

SideLaze800™ is an accessory to deliver optical energy for Cynosure 1440nm wavelength lasers and intended to be used with Cynosure 1440nm wavelength lasers' cleared indications for use, such as the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue (including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands) and laser assisted lipolysis. SideLaze800™ may be used in combination with a Cynosure SMA-compatible laser system for the same indications.

Technological Characteristics:

The SideLaze800™ option contains equivalent components and patient-contact materials as the cleared delivery accessories of Cynosure Multiwavelength Laser with 1440nm wavelength (K091537) and Cynosure Cellulaze (K102541). The fundamental scientific technology of the modified device (addition of SideLaze800™ accessory) has not changed.

Performance Standards:

This device conforms to the Laser Performance Standard (21 CFR 1040). No additional performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

Performance Data:

Performance (bench) testing summaries relating to the addition of the SideLaze800™ option is included in this submission.

Substantial Equivalence:

The SideLaze800™ option of the Cynosure 1440nm wavelength lasers is as safe and effective as the accessories cleared with the Cynosure Multiwavelength Lasers with 1440nm wavelength. The SideLaze800™ accessory option does not represent any fundamental changes in technology or any changes in indicated use, and this accessory option does not raise any additional questions of safety and effectiveness. In summary, the addition of the SideLaze800™ option used to deliver optical energy for Cynosure 1440nm wavelength lasers described in this submission is substantially equivalent to the predicate devices.

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

Cynosure, Inc.
% Ms. Irina Kulinets
Vice President, Regulatory Affairs
and Quality Systems
5 Carlisle Road
Westford, Massachusetts 01886

MAY 13 2012

Re: K121127
Trade/Device Name: SideLaze800™, Laser Beam Delivery Accessory for Cynosure 1440nm Wavelength Lasers
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: GEX
Dated: May 08, 2012
Received: May 10, 2012

Dear Ms. Kulinets:

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,

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): K121127

Device Name: SideLaze800™, laser beam delivery accessory for Cynosure 1440nm wavelength lasers

Indications for Use: SideLaze800™ is an accessory to deliver optical energy for Cynosure 1440nm wavelength lasers and intended to be used with Cynosure 1440nm wavelength lasers' cleared indications for use, such as the surgical incision, excision, vaporization, ablation, and coagulation of soft tissue (including skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs and glands) and laser assisted lipolysis. SideLaze800™ may be used in combination with a Cynosure SMA-compatible laser system for the same indications.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE) Neil R P Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices