JAN 15 2014

Section 6: 510(k) Summary

This 510(k) Summary information is submitted in accordance with the requirements of 21 C.F.R. 807.92.

807.92(a)(1) - Submitter Information	
Name	Cynosure Inc.
Address	5 Carlisle Road Westford, MA 01886
Phone number	978-367-8736
Fax number	978-256-6556
Establishment Registration Number	1222993
Name of contact person	Kevin J. O'Connell
Date prepared	January 15, 2014
807.92(a)(2) - Name of device	
Trade or proprietary name	Iluminage Skin Smoothing Laser
Common or usual name	Medical Laser System
Classification name	Light Based Over the Counter Wrinkle Reduction
Classification panel	General and Plastic Surgery
Regulation	878.4810
Product Code(s)	OHS
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Cynosure Iluminage Diode Laser, K111454
807.92(a)(4) - Device description	
	The Iluminage Skin Smoothing Laser is a battery powered, home use (OTC) diode laser. The device emits continuous wave diode laser energy for a specified period of time to a fixed area of skin. This energy triggers the body's natural response to generate new collagen, which helps tighten the skin which reduces wrinkles. The device is composed of a handpiece for delivery of laser energy, base unit for charging and storage when not in use, an A.C. charging adapter, Instructions for Use, USB data cable and carrying pouch. The handpiece contains a 1440nm laser diode light source, internal energy power source and control electronics with embedded software. The device has been modified to add user convenience features.
807.92(a)(5) Intended use of the device	

Indications for use	The Iluminage Skin Smoothing Laser is indicated for use in the treatment of periorbital and perioral wrinkles. The modifications to the device have not changed the indications for use for the device.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

Characteristic	Iluminage Diode Laser	Iluminage Skin Smoothing Laser
Device Type	Diode Laser	Diode Laser
Wavelenght (nm)	1440	1440
Fluence (J/cm^2)	3-4	3-4
Spot Size (mm)	7	7
Rep. Rate	1	1
Data acquisition	No	Yes
Handpiece charging method	In base unit	In base unit or direct connection to USB cable or power cord
Skin Contact Indicator Color	Blue	White
Energy Delivered Indicator Color	White	Blue
Arming sequence	Short, short, long button presses	One long press of 3-5 seconds

807.92(b)(1-2) Nonclinical tests submitted

Test	Result
Iluminage Software Verification	The testing confirmed that modifications made to the device were correctly implemented. This included operating the device to insure: when the revised arming sequence is followed the laser would function; treatment levels can be changed; indicators such as skin contact, battery status, treatment count and high temperature limits would function; and that data acquisition could be performed.

807.92(b)(3) Conclusions drawn from non-clinical data

Testing confirmed that the performance of the Iluminage Skin Smoothing Laser meets the product system requirements, which is based on the predicate device. Therefore, the modification resulted in a device that performs the same as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Cynosure Incorporated
Mr. Kevin J. O'Connell
Manager Regulatory Affairs
5 Carlise Road
Westford, Massachusetts 018886

January 15, 2014

Re: K133473
Trade/Device Name: Cynosure Iluminage Skin Smoothing Laser
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: OHS
Dated: December 16, 2013
Received: December 17, 2013

Dear Mr. O'Connell:

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 contact 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. 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,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
For Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____K133473_____

Device Name: Cynosure Iluminage Skin Smoothing Laser

Indications For use: The Iluminage Skin Smoothing Laser is indicated for use in the treatment of periorbital and perioral wrinkles.

PRESCRIPTION USE ____ AND/OR Over-The-Counter Use _ X
(Part 21 CFR 801 Subpart D) (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)

Neil R Ogden -S
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(Division Sign-Off) for BSA

Division of Surgical Devices

510(k) Number K133473