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

September 11, 2014

Cynosure Incorporated
Ms. Kelli McMillan
Regulatory Affairs Specialist
5 Carlisle Road
Westford, Massachusetts 01886

Re: K141425
Trade/Device Name: Cynosure Elite+ 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: GEX
Dated: August 11, 2014
Received: August 13, 2014

Dear Ms. McMillan:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141425

Device Name
Cynosure Elite+ Laser

Indications for Use *(Describe)*

755 nm:

The Cynosure Elite+ Laser is indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowting when measured 6, 9, or 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

1064 nm:

The Cynosure Elite+ Laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis 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 indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary
Elite+ Laser Special 510(k)
K141425

807.92(a)(1) Submitter Information	
Applicant	Cynosure, Inc
Address	5 Carlisle Road Westford, MA 01886
Phone Number	(781) 993-2454
Fax Number	(978) 256-6556
Establishment Registration Number	1222993
Contact Person	Kelli McMillan
Preparation Date	September 10, 2014
807.92(a)(2) Name of Device	
Trade or Proprietary Name	Elite+ Laser
Common or Usual Name	Medical Laser System
Classification	II
Regulation Name	Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology
Classification Panel	General & Plastic Surgery
Regulation	878.4810
Product Code(s)	GEX
807.92 (a)(3) Legally marketed device(s) to which equivalence is claimed	
	Apogee Elite K034030
807.92(2)(4) Device Description	
	Cynosure Elite+ laser has an Alexandrite crystal rod as the lasing medium, with a wavelength of 755 nm. The 1064 nm wavelength is generated from the Nd:YAG laser head. Laser activation is by either by finger or foot switch. The overall weight of the laser is 180 lbs and the size is 41 x 15 x 25 in (HxWxD). Electrical equipment is 208/240 VAC, single phase, 30A, 50/60 Hz. **The modifications to this device are four handpieces allowing for a larger treatment area; 18 mm, 20 mm, 22 mm and 24 mm. The 1064 Nd:YAG laser did not require any modifications to support the new handpieces. Minor modifications, including rod diameter change and lamp fill pressure change, were made to the Alexandrite laser to increase the energy to support the larger spot sizes. The software continues to control the energy based on the handpiece attached. This prevents the increase in available energy from the laser from increasing the fluence of the existing spot sizes.**
807/92(a)(5) Intended Use of the Device	
	755 nm: The Cynosure Elite+ Laser is indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowting

	when measured 6, 9, or 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I-VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles. 1064 nm: The Cynosure Elite+ Laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratosis 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 indicated for the treatment of pseudofolliculitis barbae (PFB) and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.

807.92(a)(6) Summary of the Technological Characteristics of the Device compared to the Predicate				
	Elite+ K141425		Apogee Elite K034030	
Laser Type	Alexandrite and Nd:YAG Lasers		Alexandrite and Nd:YAG Lasers	
Wavelength	755 nm	1064 nm	755 nm	1064 nm
Maximum Fluence	60 J/cm	300 J/cm	60 J/cm	300 J/cm
Repetition Rate	1 to 5 Hz	1 to 10 Hz	1 to 5 Hz	1 to 10 Hz
Pulse Duration	0.1-300 ms		0.1-300 ms	
Spot Sizes (mm)	3, 5, 7, 10, 12, 15, 18, 20, 22, 24		3, 5, 7, 10, 12.5, 15	
807.92(b)(1) Non-clinical tests submitted				
Test	**Result**			
Software	The testing confirmed that the software specifications were met.			
807.92(b)(2) Clinical tests submitted				
None				
807.92(b)(3) Conclusions drawn from non-clinical data				
Testing confirmed that the performance of the Elite+ Laser meets the product system requirements, which is based on the predicate device. Therefore, the modification resulted in a device that performs within the same specifications of the predicate device, and is therefore substantially equivalent.				