DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 24, 2014

Cynosure Incorporated
Ms. Allyson Connor
Regulatory Affairs Specialist
5 Carlisle Road
Westford, Massachusetts 01886

Re: K142376
Trade/Device Name: Palomar Icon Aesthetic System
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: ONG, GEX
Dated: August 25, 2014
Received: August 26, 2014

Dear Ms. Connor:

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

Indications for Use

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

510(k) Number *(if known)*
K142376

Device Name
Palomar Icon Aesthetic System

Indications for Use *(Describe)*

Indications for Use (Describe)

The 2940 Ablative Laser Handpiece is intended for use in surgical applications requiring the excision, incision, ablation, vaporization, and coagulation of soft tissue. Soft tissue includes skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, calculi or fragments, mucous membrane, lymph vessels and nodes, organs, and glands in the following indications: skin resurfacing, treatment of wrinkles, epidermal nevi, telangiectasia, spider veins, actinic chelitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision (including acne scars), debulking benign tumors, debulking cysts and superficial skin lesions.

The 2940 Fractional Ablative Laser Handpiece is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia.

The 1540 Fractional Non-ablative Laser Handpiece is intended for use in the coagulation of soft tissue, skin resurfacing procedures as well as treatment of melasma, striae, acne scars and surgical scars.

The 1440 Fractional Non-ablative Laser Handpiece is intended for use in dermatological procedures requiring coagulation of soft tissue and skin resurfacing procedures.

The 1540 Fractional Non-ablative Laser and 2940 Fractional Abaltive Laser Handpiece combined treatment is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, dyschromia and pigmented lesions.

The 1440 Fractional Non-ablative Laser Handpiece and 2940 Fractional Ablative Laser Handpiece combined treatment is intended for dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularties, dyschromia and pigmented lesions.

The MaxIR Handpiece is intended for photocoagulation of soft tissue in dermatologic applications. In addition, it is intended to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, the temporary relief of minor joint pain associated with arthritis, the temporary increase in local circulation where applied, and the relaxation of muscles. In addition, it may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

The 1064 Laser Handpiece is intended for the removal of unwanted hair for skin types I-VI, and to effect stable long-term permanent hair reduction; treatment of benign pigmented lesions such as, but not limited to, senile lentigines (age spots), solar lentigos (sun spots), pigmented seborrheic keratosis; tattoos (significant reduction in the intensity of black and/or blue-black tattoos); pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser/light treatments; treatment of vascular lesions such as but not limited to, port wine stains, hemangiomas, telangiectasias, rosacea, venus lake, facial and leg veins; reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar; coagulation and hemostasis of soft tissue; treatment of wrinkles and pseudofolliculitis barbae (PFB).

The Max series Intense Pulsed Light Handpieces are intended for the treatment of inflammatory acne (acne vulgaris) and

for the treatment of benign pigmented epidermal and cutaneous lesions, including warts, scars and striae, removal of unwanted hair from skin types I-VI, and to effect stable long-term, or permanent, hair reduction; treatment of benign pigmented lesions, including port wine stains, hemangiomas, aniomas, telangiectasias, rosacea, facial and leg veins.

The Skintel Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot starting fluence.

PSC Publishing Services (301) 443-6740 EF

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary:

A summary of 510(k) safety and effectiveness information 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
Name of contact person	Allyson Connor
Telephone	978-367-8736
Fax number	978-256-6556
Email	aconnor@cynosure.com
Establishment Registration Number	1222993
Date prepared	8/25/14
807.92(a)(2) - Name of device	
Trade or proprietary name	Palomar Icon® Aesthetic System
Common or usual name	Light and Laser System
Classification name	Instrument, Surgical, Powered, laser
Classification panel	General and Plastic Surgery
Regulation	878.4810
Product Code(s)	GEX, ONG
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Palomar Icon® Aesthetic System, K110907
807.92(a)(4) - Device description	
	The Palomar Icon® Aesthetic System including attachable treatment handpieces is designed to deliver pulses of broadband incoherent or laser light to a predetermined target site. The Palomar Icon® Aesthetic System consists of three stacking modules that contain an internal power supply, control electronics, Chiller Module, Heat Exchanger Module, Base Module, remote interlock, emergency-off button, footswitch, power control, and front panel monitor with indicators. They system includes multiple treatment hadnpieces attached to the Base Module. Each Handpiece provides laser energy at a specific wavelength or Intense Pulsed Light (IPL) at a specific range.
807.92(a)(5) Intended use of the device	

Indications for use

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The Skintel Reader is intended as an objective measurement tool for examining skin melanin content for determining and setting a test spot staring fluence.

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

	2940 Fractional Ablative Laser Handpiece (K110907)	**2940 Fraction Ablative Laser Handpiece (Modified)**
Parameter	**Description**	**Description**
Laser Type	Erbium:YAG (Er:YAG)	Erbium:YAG (Er:YAG)
Wavelength	2940 nm	2940 nm

Fluence (J/cm2)	Optic	Energy (mJ/mB)	Microbeam Density	Pitch (distance between microcolumns)	Optic	Energy (mJ/mB)	Microbeam Density	Pitch (distance between microcolumns)
	Silver (Groove ™ Optic)	2-5.5 mJ/0.1mm	N/A	1350 µm (grooves)	Silver (Groove ™ Optic)	2-5.5 mJ/0.1mm	N/A	1350 µm (grooves)
	Blue 450 Fractional Optic	3-9 mJ	469 mB/cm^2	450 µm	Blue 450 Fractional Optic	3-9 mJ	469 mB/cm^2	450 µm
	Green 1200 Fractional	8-24 mJ	178 mB/cm^2	750 µm	Green 1200 Fractional	8-24 mJ	178 mB/cm^2	750 µm
	Red 140 Fractional	3-9 mJ	169 mB/cm^2	750 µm	Red 140 Fractional	3-9 mJ	169 mB/cm^2	750 µm
	Purple Flatbeam	25 J/cm^2 – 70 J/cm^2	N/A	N/A	Purple Flatbeam	25 J/cm^2 – 70 J/cm^2	N/A	N/A
Spot Size (mm) and Treatment Zone	6 x 6 mm and 10 x 10 mm, depending on the Optic Flatbeam: 2 mm				6 x 6 mm and 10 x 10 mm, depending on the Optic Flatbeam: 2 mm			
Pulse Width (ms)	.25, 3, 5 ms				25, 3, 5 ms			
Delivery System	Microbeams of light transmitted via a microlens array in the interchangeable Optic.				Microbeams of light transmitted via a microlens array in the interchangeable Optic.			
Actuator	Foot pedal				Foot pedal			

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

Test	Sterilization Validation

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

An Autoclave Sterilization Validation of the 10 x 10 and 6 x 6 Focal Guide Assemblies was conducted using Steam Sterilization Validation Procedure. The Focal Guides were originally factory-sterilized by gamma sterilization and the intent is to provide the device to the customer non-sterile, with instructions for on-site autoclave sterilization. The test articles, negative controls, and environmental controls all exhibited no growth G. stearothermophilus after being subjected to 3 half cycle rounds of the gravity cycle settings described in ETR-191, Autoclave Sterilization Validation of 2940 Handpiece Focal Guides, meeting an SAL of $\leq 10^{-6}$. The test articles also passed validation of the specified dry time (15 minutes, minimum), as no residual moisture was detected after being subjected to the full gravity cycle settings. Functional testing shows that the sterilization does not affect the function of the device.