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

May 17, 2016

Cynosure, Inc
Ms. Amy Tannenbaum
Regulatory Affairs Specialist
5 Carlisle Road
Westford, Massachusetts 01886

Re: K160480
Trade/Device Name: PicoSure Workstation
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: February 19, 2016
Received: February 22, 2016

Dear Ms. Tannenbaum:

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" (21 CFR 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,

Jennifer R. Stevenson -A

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)*
K160480

Device Name
PicoSure Workstation with 1064 nm Laser Delivery System

Indications for Use *(Describe)*

755 nm:
The PicoSure Workstation is indicated for tattoo and benign pigmented lesions removal. The PicoSure workstation with the 2mm and 6mm hand pieces and the Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I - IV.

532 nm:
The PicoSure 532 nm Laser Delivery System is indicated for tattoo removal in Skin Types I - III.

1064 nm:
The PicoSure 1064 nm Laser Delivery System is indicated for tattoo and benign pigmented lesions removal.

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PicoSure™ Workstation
510(k) Summary
KPending

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	Amy Tannenbaum
Preparation Date	February 19, 2016
807.92(a)(2) Name of Device	
Trade or Proprietary Name	PicoSure Workstation with 532 and 1064 nm Laser Delivery System
Common or Usual Name	Medical Laser System
Classification Name	Powered Laser Surgical Instrument
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	
	PicoSure Workstation K143105 RevLite Q-Switched Nd:YAG Laser System K133254
807.92(a)(4) Device Description	
	The PicoSure™ workstation is a high-powered, Alexandrite system that delivers laser energy in the 755-nm nominal wavelength. The system offers fast and efficient treatment through a variety of spot sizes, fluences and repetition rates. Laser activation is by footswitch. In addition to the 755 nm handpiece, optional 532 nm Laser Delivery System and/or 1064 nm Laser Delivery System can replace the 755 nm handpiece at the distal end of the articulated arm. These Delivery Systems convert the 755 nm laser energy into a 532 nm wavelength or a 1064 nm wavelength and are available in multiple spot sizes.
807.92(a)(5) Intended Use of the Device	
	755 nm: The PicoSure workstation is indicated for tattoo and benign pigmented lesions removal. The PicoSure workstation with the 3mm and 6mm handpieces and the Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I-IV. 532 nm: The PicoSure 532 nm Laser Delivery System is indicated for tattoo removal in Skin Types I - III. 1064 nm: The PicoSure 1064 nm Laser Delivery System is indicated for tattoo and benign pigmented lesions removal.

	The modifications to the device have not changed the indications for use for the 755 nm or 532 nm wavelength.

807.92(a)(6) Summary of the Technological Characteristics of the Device Compared to the Predicate						
	PicoSure™ Workstation (KPending)			PicoSure Workstation (K143105)		RevLite (K133254)
Laser Type	$Nd:YVO_4$	Frequency doubled $Nd:YVO_4$	Alexandrite	Frequency doubled 1064 nm solid state laser	Alexandrite	Nd:YAG
Wavelength	1064 nm	532 nm	755 nm	532 nm	755 nm	1064 nm/532 nm
Maximum Average Fluence	3.6 J/cm^2	1.5 J/cm^2	6.37 J/cm^2	1.5 J/cm^2	6.37 J/cm^2	12 J/cm^2 @ 1064 nm 5 J/cm^2 @ 532 nm
Repetition Rate	1, 2.5, 5, 10 Hz	1, 2.5, 5, 10 Hz	Single, 1, 2.5, 5, 10 Hz	1, 2.5, 5, 10 Hz	Single shot, or 1, 2.5, 5, 10 Hz	Single shot, 1, 2, 5, 10 Hz
Pulse Duration	450 - 900 ps	450 - 900 ps	450 - 900 ps	≤ 900 ps		≤ 20 ns
Spot Sizes (mm)	Fixed 1.4 – 4.0 mm	Fixed 1.5 – 3.5 mm	Zoom 2-6 mm, Fixed 6, 8, 10 mm	Fixed 1.5 – 3.5 mm	Zoom 2-6 mm, Fixed 2, 3, 4, 6, 8, 10 mm	2-8.5 mm, 0.1 mm increments
807.92(b)(1) Non-clinical tests submitted						
Software verification and validation testing to support the 1064 nm Laser Delivery System was successfully completed.						
807.92(b)(2) Clinical tests submitted						
The study was performed using 66 subjects with a total of 79 tattoos. Subjects were ages 21 – 60. Subjects received up to 12 treatments, one every 6 weeks (+/- 2 weeks). Subjects were divided into two groups and treated exclusively with PicoSure, or their tattoo was split into two treatments areas, and treated with PicoSure and the predicate device. Three blinded reviewers performed an evaluation of photographs using a 6 points categorical efficacy scoring scale as well as rating the clearance of individual colors in the tattoos. Mean scores for all three evaluators were calculated per subject to determine overall mean scores. The results of the blinded evaluation were subjects treated with PicoSure were rated 4.1/6 overall mean score, showing the PicoSure to be as effective as the predicate device RevLite, which had an average score of 3.7/6. There were no deaths, serious adverse events (SAE) or unanticipated adverse device effects (UADEs) reported in this study. The primary objectives of the study; to assess overall treatment efficacy through blinded photographic evaluation using a 6 point scale to grade improvement, assess safety of the PicoSure laser through the recording of side effects during the course of the study, and compare efficacy of the PicoSure laser to the predicate device in a subset of patients, have been met.						
807.92(b)(3) Conclusions drawn from clinical and non-clinical tests submitted						
Testing confirmed that the PicoSure workstation with the 532 and 1064 nm Laser Delivery System is safe and effective in the removal of tattoos.						