February 7, 2018

Cynosure, Inc
Avinash Purohit
Regulatory Affairs Specialist
5 Caelisle Road
Westford, Massachusetts 01886

Re: K173199
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: September 28, 2017
Received: October 2, 2017

Dear Avinash Purohit:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173199

Device Name
PicoSure Workstation

Indications for Use *(Describe)*

755nm:
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.

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

1064nm:
The PicoSure 1064nm 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.

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510(k) Summary for the PicoSure Workstation	
807.92(a)(1) Submitter Information	
Applicant	Cynosure, Inc.
Address	5 Carlisle Road Westford, MA 01886
Phone Number	(978) 367-2450
Fax Number	(978) 256-6556
Establishment Registration Number	1222993
Contact Person	Mr. Avinash Purohit
Preparation Date	28 September 2017
807.92(a)(2) Name of Device	
Trade or Proprietary Name	PicoSure Workstation
Common or Usual Name	Laser Workstation
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 - **K160480** 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 755nm handpiece, optional 532nm Laser Delivery System and/or 1064nm Laser Delivery System can replace the 755nm handpiece at the distal end of the articulated arm. These Delivery Systems convert the 755nm laser energy into a 532nm wavelength or a 1064 nm wavelength, and are available in multiple spot sizes.
807.92(a)(5) Intended Use of the Device	
	<u>755 nm:</u> The PicoSure Workstation is indicated for tattoo and benign pigmented lesions removal. The PicoSure workstation with the 2mm and 6mm handpieces and the Focus Array are indicated for the treatment of acne scars and wrinkles in Skin Types I-IV. <u>532 nm:</u> The PicoSure 532 nm delivery system is indicated for tattoo removal and benign pigmented lesion removal in Skin Types I-III. <u>1064 nm:</u> The PicoSure 1064 nm Laser Delivery System is indicated for tattoo and benign pigmented lesions removal.

807.92(a)(6) Summary of the Technological Characteristics of the Device Compared to the Predicate								
510(k) Number	PicoSure Workstation (KPending)			PicoSure Workstation (K160480)			RevLite Q-switched Nd:YAG Laser System (K133254)	
Laser Type	$Nd:YVO_4$	Frequency doubled $Nd:YVO_4$	Alexandrite	$Nd:YVO_4$	Frequency doubled $Nd:YVO_4$	Alexandrite	Flashlamp Excited Q-Switched Nd:YAG	
Wavelength (nm)	1064 nm	532 nm	755 nm	1064 nm	532 nm	755 nm	1064 nm	532 nm
Maximum Average Fluence (J/cm^2)	3.6 J/cm^2	1.5 J/cm^2	6.37 J/cm^2	3.6 J/cm^2	1.5 J/cm^2	6.37 J/cm^2	12 J/cm^2	5 J/cm^2
Repetition Rate (Hz)	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	1, 2.5, 5, 10 Hz	Single, 1, 2.5, 5, 10 Hz	Single Shot, 1, 2, 5, 10 Hz	
Pulse Duration	450-900 ps			450-900 ps			7 – 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 1.4 – 4.0 mm	Fixed 1.5 – 3.5 mm	Zoom 2-6 mm, Fixed 6, 8, 10 mm	2 – 8.5 mm with 0.1 mm increments	

807.92(b)(1) Non-clinical tests submitted

For this submission, software and electrical safety testing were not necessary for the expanded indication. However, incremental software updates required testing and was completed successfully. With regard to electrical safety, the device experienced only constructional changes as part of normal maintenance, so additional testing was not required. EMC testing was still performed on two components added to improve product reliability. All changes have been analyzed and successfully tested where necessary. Therefore, these software updates/constructional changes do not affect the safety and efficacy of the PicoSure Workstation.

807.92(b)(2) Clinical tests submitted

A prospective clinical study was conducted using 30 treatment areas (2 areas for each of the 15 subjects), both male and female, in which the removal of benign pigmented lesions was performed using the PicoSure Workstation's 532nm Delivery System. Subjects involved in the study were 93% female, 7% male, and were between the ages (53 – 70) years old. They were a range of Fitzpatrick Skin Types I-III. All potential subjects were evaluated against the study's inclusion/exclusion criteria to determine enrollment eligibility. During the course of the study, subjects received up to 4 treatments that were 4 weeks (+/- 2) apart using the PicoSure Workstation's 532nm wavelength laser energy. These subjects were then followed up on a (1 month) and (3 month) timeframe to assess for any adverse patient impacts at the treatment site. The clinical efficacy endpoint was evaluated through comparison of the pre-treatment and post-treatment images by three blinded, board certified Dermatologists as

	independent reviewers. The clinical investigator evaluated progress via the GAIS [Global Aesthetic Improvement Scale], where 91.1% of the subjects at [1 month follow-up] had a score of "1 – Very Much Improved". The safety endpoint sought to collect adverse events over the course of the study. All adverse effects from the clinical study were transient (resolving in 2-11 days) in form of redness, crusting, pain, itching, and blistering. These are all expected side effects from laser treatments. The objectives of the study were met and concluded that the use of PicoSure's 532nm Delivery System is a safe and effective method for the removal of benign pigmented lesions in Skin Types I-III.
	807.92(b)(3) Conclusions drawn from clinical and non-clinical tests submitted
	The non-clinical data demonstrates support for safety and effectiveness of the device in regards to hardware and software to perform as intended for treatment conditions. The clinical study demonstrated that the PicoSure Workstation using the 532nm Delivery System operated as expected and delivered safe and effective results with minimal side effects in subjects being treated for benign pigmented lesion removal in Skin Types I-III.