March 30, 2021

Cynosure LLC
Michael King
Regulatory Affairs Specialist III
5 Carlisle Road
Westford, Massachusetts 01886

Re: K210226
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: January 26, 2021
Received: January 28, 2021

Dear Michael King:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210226

Device Name
PicoSure™ Workstation

Indications for Use *(Describe)*

755nm:
The PicoSure Workstation is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota, Hori macules (nevus of Hori), and Melasma. 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 532-nm delivery system is indicated for tattoo removal and benign pigmented lesions removal in Skin Types I-III.

1064nm:
The PicoSure 1064-nm 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.

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K210226 – 510(k) Summary for Cynosure PicoSure

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) Submitter Information	
Applicant	Cynosure, LLC
Address	5 Carlisle Road, Westford MA, 01886
Phone Number	781-993-2454
Fax Number	978-256-6556
Establishment Registration Number	1222993
Contact Person	Michael King
Preparation Date	March 22, 2021
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	21 CFR 878.4810
Regulatory Class	II
Product Code(s)	GEX
807.92 (a)(3) Legally marketed device(s) to which equivalence is claimed	
Predicate Device	PicoSure Workstation (K173199)
Reference Device	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 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	
	755nm: The PicoSure Workstation is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota, Hori macules (nevus of Hori), and Melasma. 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 532-nm delivery system is indicated for tattoo removal and benign pigmented lesions removal in Skin Types I-III. 1064nm: The PicoSure 1064-nm 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	
	There have been no changes to the technological characteristics of the device compared to the predicate PicoSure Workstation (K173199). A review of clinical literature was conducted to support the addition of specific indications nevus of Ota, Hori macules (nevus of Hori), and melasma to the general indications for use of the PicoSure Workstation. Please refer to the Laser System Specification comparison table below. RevLite (K133254) is being included as a reference device for this submission. PicoSure was originally cleared under K121346, using RevLite as a predicate device.
807.92(b)(1) Non-clinical tests submitted– N/A – No non-clinical tests submitted	
807.92(b)(2) Clinical tests submitted – A literature search was conducted to identify peer reviewed, published articles in which the Picosure device was used to treat specific benign pigmented lesions nevus of Ota, Hori macules (nevus of Hori), and melasma. Six articles were identified that reported prospective studies that were controlled or randomized and that treated at least ten individuals with the target pigmented lesion using the PicoSure at 755nm. These studies reported acceptable clinical effectiveness and safety. There were no serious adverse events reported in the publications. Side effects reported in the studies were primarily transient and included common acceptable side effects for laser treatments as described in the product labeling.	

807.92(b)(3) Conclusions drawn from clinical and non-clinical tests submitted – The clinical data submitted demonstrates that the PicoSure device utilizing the 755nm wavelength is safe and effective for the treatment of specific benign pigmented lesions nevus of Ota, Hori macules (nevus of Hori), and melasma. We therefore conclude that the subject device is substantially equivalent to the PicoSure Workstation predicate device cleared in K173199.

Indications for Use

PicoSure Workstation (K210226)	PicoSure Workstation (K173199)	RevLite Q-Switched Nd:YAG Laser System (K133254)
755nm: The PicoSure Workstation is indicated for tattoo and benign pigmented lesions removal including but not limited to: Nevus of Ota, Hori macules (nevus of Hori), and Melasma. 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 532-nm delivery system is indicated for tattoo removal and benign pigmented lesions removal in Skin Types I- III. 1064nm: The PicoSure 1064-nm delivery system is indicated for tattoo and benign pigmented lesions removal.	755 nm: 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. 532 nm: The PicoSure 532 nm Laser Delivery System is indicated for tattoo removal and benign pigmented lesion removal in Skin Types I-III. 1064 nm: The PicoSure 1064 nm Laser Delivery System is indicated for tattoo and benign pigmented lesions removal.	1064 nm: Tattoo Removal (dark ink: blue and black) Dermal Pigmented Lesions; including but not limited to; Nevus of Ota, Lentigines, Nevi, Melasma and Café-au-lait Removal or lightening of hair with or without adjuvant preparation. Skin Resurfacing for Acne Scars and Wrinkles Benign cutaneous lesions; including but not limited to: striae and scars (excludes the 650nm wavelength) Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength) 532nm: (nominal delivered energy of 585nm and 650nm with the Optional Multilite Dye Laser Handpiece) Tattoo removal (light ink: red, sky blue, green) Vascular lesions including but not limited to: port wine birthmarks, telangiectasias, spider angioma, cherry angioma, spider nevi Epidermal Pigmented lesions; including, but not limited to: café-au-lait birthmarks, solar lentigines, senile lentigines, Becker's nevi, Freckles, Nevus spilus, seborrheic keratosis Skin Resurfacing for Acne Scars and Winkles Benign cutaneous lesions; including but not limited: striae and scars (excludes the 650nm wavelength) Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar (excludes the 650nm wavelength)

Laser System Specifications

Description	PicoSure Workstation (K210226)			PicoSure Workstation (K173199)			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	Nd:YAG	
Wavelength (nm)	1064 nm	532 nm	755 nm	1064 nm	532 nm	755 nm	1064nm	532nm
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	8 J/cm^2	
Repetition Rate (Hz)	1, 2.5, 5,10	1, 2.5, 5, 10	Single Shot, 1, 2.5, 5, 10	1, 2.5, 5,10	1, 2.5, 5, 10	Single Shot, 1, 2.5, 5, 10	Single shot, 1, 2, 5, 10 Hz	
Pulse Width	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	2-8.5mm range with 0.1mm increments	
Rx/OTC	Prescription			Prescription			Prescription	
Patient Contacting Material	316 Stainless Steel			316 Stainless Steel			304 Stainless Steel Anodized Aluminum	
Electrical Power	200-240 V~, 4.5 kVA, 50/60 Hz, Single Phase			200-240 V~, 4.5 kVA, 50/60 Hz, Single Phase			AC 230 V, 50/60 Hz	
Dimensions	43 in (109 cm) H x 22in (56cm) x 42in (107cm) Note: Height with arm extended 62in (158cm)			43 in (109 cm) H x 22in (56cm) x 42in (107cm) Note: Height with arm extended 62in (158cm)			31.8” (H) x 12” (W) x 28.5” (D)	
Weight	375 lb (171 kg)			375 lb (171 kg)			131 lbs	