June 17, 2026

Cynosure, LLC
Sean Reynolds
Sr. Manager, Regulatory Affairs
5 Carlisle Rd.
Wesford, Massachusetts 01886

Re: K261570
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: May 11, 2026
Received: May 12, 2026

Dear Sean Reynolds:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2026.06.17 16:00:43 -04'00'

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261570

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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K261570 – Special 510(k) Summary

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	978-842-9864
Fax Number	N/A
Establishment Registration Number	1222993
Contact Person	Sean Reynolds Sr. Manager, Regulatory Affairs 3/5 Carlisle Road Westford, MA, 01886
Preparation Date	June 15, 2026
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 Devices	PicoSure Workstation (K210226)

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 (K210226).

Description	**PicoSure Workstation (KPending)**	**PicoSure Workstation K210226**
Laser Type	Nd: YVO_4, Frequency Doubled Nd: YVO_4, and Alexandrite laser	Nd: YVO_4, Frequency Doubled Nd: YVO_4, and Alexandrite laser
Wavelength	Nd: YVO_4 (1064 nm), Frequency Doubled Nd: YVO_4 (532 nm), and Alexandrite (755 nm) laser	Nd: YVO_4 (1064 nm), Frequency Doubled Nd: YVO_4 (532 nm), and Alexandrite (755 nm) laser
Delivery System	Optic Fiber	Optical Fiber

Treatment Activation	Footswitch	Footswitch
Rx/OTC	Prescription	Prescription
Maximum Fluence	6.37 J/cm2	6.37 J/cm2
Repetition Rate	Single Shot, 1, 2.5, 5, 10 Hz	Single Shot, 1, 2.5, 5, 10 Hz
Pulse Width	450 – 900 ps	450 – 900 ps
Handpiece (Spot) Size	**755 nm:** 5mm, 6mm, 8mm, 10mm, Platinum focus, Zoom: 2.0-6.0mm **532nm:** 1.5mm, 2.0mm **1064nm:** 2.0mm, 2.5mm	**755 nm:** 5mm, 6mm, 8mm, 10mm, Platinum focus, Zoom: 2.0-6.0mm **532nm:** 1.5mm, 2.0mm **1064nm:** 2.0mm, 2.5mm
Beam Divergence	Full Angle **755nm:** 13mRad @ 5mm 13mRad @ 6mm 4mRad @ 8mm 13mRad @ 10mm Zoom HP: 70 – 23mRad @ 2.0 – 6.0mm **532nm:** 140mRad @ 1.5mm 160mRad @ 2.0mm **1064nm:** 100mRad @ 2.0mm 90mRad @ 2.5mm	Full Angle **755nm:** 13mRad @ 5mm 13mRad @ 6mm 4mRad @ 8mm 13mRad @ 10mm Zoom HP: 70 – 23mRad @ 2.0 – 6.0mm **532nm:** 140mRad @ 1.5mm 160mRad @ 2.0mm **1064nm:** 100mRad @ 2.0mm 90mRad @ 2.5mm
Patient Contacting Material	**Handpiece Tips:** 316 Stainless Steel	**Handpiece Tips:** 316 Stainless Steel
Input Voltage	200-240 V~, 4.5 kVA, 50/60 Hz, Single Phase	200-240 V~, 4.5 kVA, 50/60 Hz, Single Phase
Current	30 Amp Dedicated Outlet	30 Amp Dedicated Outlet
Dimensions	43 in (109 cm) H x 22in (56cm) x 42in (107cm) Note: Height with arm extended 72in (183cm)	43 in (109 cm) H x 22in (56cm) x 42in (107cm) Note: Height with arm extended 62in (158cm)
Weight	375 lb. (171 kg)	375 lb. (171 kg)

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

The following verification and validation activities have been performed on the modified device.

Risk analysis according to the FDA recognized consensus standard ISO 14971:2019

EC 60601-1:2020-08 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.

IEC 60601-1-2 Ed. 4.1 :2020-09 – Medical electrical equipment – part 1-2: General Requirements for Basic Safety and Essential Performance– Collateral standard: Electromagnetic Disturbances – Requirements and tests IEC 60601-2-22 Edition 3.1 2012-10 - Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements
807.92(b)(2) Clinical tests submitted –No clinical tests submitted
807.92(b)(3) Conclusions drawn from clinical and non-clinical tests submitted The subject device PicoSure™ Workstation is substantially equivalent to the predicate device K210226.