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

May 23, 2016

Cynosure, Incorporated
Ms. Irina Kulinets
Vice President of Regulatory Affairs and Quality Systems
5 Carlisle Road,
Westford, Massachusetts, 01886

Re: K121346
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: November 8, 2012
Received: November 9, 2012

Dear Ms. Kulinets:

This letter corrects our substantially equivalent letter of November 27, 2012.

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,

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)*
K121346

Device Name
Picosure™ workstation

Indications for Use *(Describe)*
The PicoSure™ workstation 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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510(k) Summary

510(K) Owner:	CYNOSURE, INC. 5 Carlisle Road Westford, MA 01886 Telephone: 978-256-4200 Fax: 978 256 6556
Contact:	Irina Kulinets VP of Regulatory Affairs and Quality Systems CYNOSURE, INC. 5 Carlisle Road Westford, MA 01886
Submitter:	Connie Hoy SVP of Regulatory Affairs and Quality Systems CYNOSURE, INC. 5 Carlisle Road Westford, MA 01886
Manufacturer:	CYNOSURE, INC. 5 Carlisle Road Westford, MA 01886
Date Prepared:	March 29, 2016
Trade name:	PicoSure™ workstation
Common name:	Powered Laser Surgical Instrument (Laser for Surgery and Dermatology)
Classification name:	21 CFR 878.4810
Product Code(s):	GEX (Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology)
Classification:	Class II

Review Panel: General & Plastic Surgery

Predicate Devices (Claiming Substantial Equivalence):

K992814 Cynosure Accolade/Accolade II Laser
K103118 HOYA ConBio RevLite

Summary Description of the Device:

The PicoSure™ workstation is a high-powered, laser system that delivers energy in the 755-nm wavelength. Same as its predicates, the PicoSure™ workstation is intended for tattoos and benign pigmented lesions removal. The combination of wavelength, pulse duration and energy fluence are disrupting the tattoo dye or pigment particles under the skin without harming the surrounding tissue. The fragmented dye or pigment particles eventually surface and fade as the epidermal layer of the skin is renewed.

Intended Use / Indications for Use:

The PicoSure™ workstation is indicated for tattoo and benign pigmented lesions removal.

Technological Characteristics:

The PicoSure™ workstation contains equivalent basic technology, components and patient-contact materials as the FDA cleared Cynosure Accolade/Accolade II laser (K992814 and K072868). The fundamental scientific technology of the PicoSure™ workstation is substantially equivalent to the FDA cleared Cynosure Accolade/Accolade II laser (K992814 and K072868).

Performance Standards:

This device conforms to the Laser Performance Standard (21 CFR 1040). No additional performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices.

Performance Data: Non-clinical testing

Performance (bench and animal) testing summaries are included in this submission. Bench testing included:

- Design verification which includes software and hardware verification
- Design validation which includes software and hardware validation
- Production verification which includes in-process inspection and test

Animal data has been used to establish the device safety. A study examined the effect of the PicoSure™ workstation in an animal model (porcine study).

Performance Data: Clinical testing

Three clinical studies (two controlled and one uncontrolled) were presented in the submission to confirm safety and effectiveness of the device in the tattoo removal. Number of treatments varied in the studies from 4 to 10 sessions. The device effectiveness in removal tattoos was assessed by the evaluation before-and-after photos and calculation the % of tattoo clearance at the end of study for each treatment area. Subject and physician satisfaction with the treatment results was also surveyed and analyzed.

The device safety was evaluated by the incidence, timing, severity of treatment-emergent adverse events were categorized and summarized.

The device was found to be safe and effective, with high level of overall tattoo clearance and ''extreme,'' physician satisfaction (physician evaluation) and, additionally, demonstrated more significant % of highest clearance score than control device in controlled studies.

Treatment-emergent adverse events were recorded and evaluated in all studies. All treatment arms had a comparable safety profile. None of the events were classified as adverse device reaction. No serious or unexpected adverse events were reported. The majority of reported adverse events across the studies were of mild severity; no severe adverse events were reported in any group. The most common reactions were pain and blistering.

Substantial Equivalence:

The Cynosure PicoSure™ workstation is as safe and effective as its predicate devices currently cleared for the same indications. The Cynosure PicoSure™ workstation is substantially equivalent to the predicate device(s) as shown in the table below and does not does not raise any additional questions of safety and effectiveness. Substantial Equivalence Table is provided below.

Device Comparison Table - Substantial Equivalence

	Proposed Device	Predicate Device	Predicate Device
510(k) #		K992814	K103118
Company	CYNOSURE, INC.	CYNOSURE, INC.	HOYA ConBio
Name	Cynosure PicoSure™ workstation	Cynosure Accolade	RevLite
Laser Type	Flashlamp excited Q-switched alexandrite	Flashlamp excited Q-switched alexandrite	Flashlamp excited Q-switched alexandrite
Nominal Wavelength	755nm	755nm	532 nm, 585 nm 650 nm, & 1064 nm
Energy per pulse	0.2 J/cm2	0.57 J/cm2	0.85 J/cm2
Maximum Average Fluence	6.37 J/cm^2	7.5 J/cm^2	12 J/ cm^2 (1064nm) 5 J/ cm^2 (532nm) 10 J/ cm^2 (585nm) 6 J/ cm^2 (650 nm) 1.2 J/ cm^2 (532Lite)
Rate	Single pulse, or 1, 2.5, 5, or 10 pulse(s) per second (Hz)	Single pulse, or 1,2,5, or 10 pulse(s) per second (Hz)	Single & double pulse, 1, 2, 5, & 10 Hz pulses per second
Pulse Width	450ps – 900ps	45-75 ns	5-20 ns
Spot Sizes	Zoom 2-6 mm, Fixed 2, 3, 3, 4, 6, 8, 10 mm	Fixed 2.4, 3, 4 mm	Fixed 2 – 8 mm (varies by wavelength)

Conclusion:

PicoSure™ workstation is as safe and efficient as its predicate devices.