January 29, 2018

Sciton, Inc
Mr.Jay Patel
VP of Regulatory Affairs
925 Commercial Street
Palo Alto, California 94303

Re: K173285
Trade/Device Name: Joule System
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: December 29, 2017
Received: January 4, 2018

Dear Mr. Patel:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173285

Device Name
JOULE ProFractional System

Indications for Use *(Describe)*
The Joule 2940 nm ProFractional System with its accessories is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, benign pigmented lesions, and vascular dyschromia.

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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Attachment IV

510(k) Summary

Submitter:	Sciton, Inc.
Address:	925 Commercial Street, Palo Alto, CA 94303
Phone:	(650) 493-9155
Fax :	(650) 493-9146
Contact Person:	Jay M. Patel, VP of Regulatory Affairs
Date Prepared:	January 9, 2018
Device Trade Name:	JOULE ProFractional System
Common Name:	Laser Powered Surgical Device (and Accessories)
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Product Code:	GEX
Legally Marketed Predicate Device:	K101916: Joule Multi-Platform System K081352: Profile Multi-Platform System K100270: Artisan Aesthetic System K110907: Palomar Icon Aesthetic System K142376: Palomar Icon Aesthetic System
Description of JOULE ProFractional System:	The JOULE ProFractional System consists of a console and laser deliver accessories. It uses focusing optics to deliver thermal energy to the treatment site. The control console houses the power supply, cooling system, articulated arm delivery system and/or fiber optic arm delivery system with a handpiece. The user activates laser emission by means of a footswitch.
Intended Use:	The Joule 2940 nm ProFractional System with its accessories is intended for use in dermatological procedures requiring coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, benign pigmented lesions, and vascular dyschromia.
Technological Characteristics:	The JOULE 2940 nm ProFractional System shares the same indications for use, and as noted below, shares similar design features (including wavelength, laser medium and delivery systems, power supply, cooling and control system), functional features (including power output, repetition rate, energy, spot size and fluence), and is therefore substantially equivalent to the above legally marketed predicate devices.

2940 nm Laser System						
Specification	**Predicate Devices**				**This Application**	**Substantially Equivalent**
	JOULE Multi-Platform System	**Profile ProFractional**	**Palomar LUX2940 Fractional Handpiece**	**Cynosure**	**Joule 2940 Fractional Handpiece**	
Indications for Use	The JOULE 2940 nm Multi-Platform System with ProFractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing, ablation and coagulation of soft tissue.	Coagulation and resurfacing of soft tissue.	Coagulation, resurfacing and ablation of soft tissue, treatment of wrinkles, pigmented lesions and vascular dyschromia.	Coagulation, resurfacing, and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, pigmented lesions, and vascular dyschromia	Coagulation, resurfacing and ablation of soft tissue. Procedures include skin resurfacing and treatment of wrinkles, rhytides, furrows, fine lines, textural irregularities, benign pigmented lesions, and vascular dyschromia	Yes
Ref. 510(k)	K101916	K081352	K100270, K110907	K142376	K173285	--
Energy Source	2940 nm Er:YAG	2940 nm Er:YAG	2940 nm Er:YAG	2940 nm Er:YAG	2940 nm Er:YAG	Yes
Spot Size	1.3x1.3mm to 20x20mm	Up to 20 x 20 mm	Up to 10 x 10 mm	Up to 10 x 10 mm	1.3x1.3mm to 20x20mm	Yes
Wavelength	2940 nm	2940 nm	2940 nm	2940 nm	2940 nm	Yes
Maximum Repetition Rate	Up to 3 Hz	Up to 2 Hz	Up to 3 Hz	--	Up to 3 Hz	Yes
Pulse Duration	0.5 to 1.5 msec	0.5 to 1.5 msec	Up to 5 msec	Up to 5 ms	0.5 to 1.5 msec	Yes
Energy	Up to 70 mJ/microbeam	Up to 70 mJ/microbeam	Up to 24 mJ/microbeam	Up to 70 mJ/microbeam	Up to 70 mJ/microbeam	Yes
Utilities	230 VAC/25A, 50/60 Hz	230 VAC/25A, 50/60 Hz	100-240 VAC, 50/60 Hz	100-240 VAC, 50/60 Hz	230 VAC/25A, 50/60 Hz	Yes
Aiming Beam	Red/Green	Red/Green	--	--	--	Yes
Delivery System	Articulated Arm or Fiber optic	Articulated Arm or Fiber optic	Fiber optic	Fiber optic	Articulated Arm	Yes
Cooling System	Water to Air	Water to Air	Water to Air	Water to Air	Water to Air	Yes
Control System	Microprocessor	Microprocessor	Microprocessor	Microprocessor	Microprocessor	Yes
Energy Monitor	Display Indicates Energy Delivered to Tissue	Display Indicates Energy Delivered to Tissue	Display Indicates Energy Delivered to Tissue	Display Indicates Energy Delivered to Tissue	Display Indicates Energy Delivered to Tissue	Yes
Safety	Safety Eyewear and Remote Interlock Connector	Safety Eyewear and Remote Interlock Connector	--	--	Safety Eyewear and Remote Interlock Connector	Yes
Console Dimensions	14” x 21” x 41” high	14” x 21” x 41” high	--	23” x 22” x 41” high	14” x 21” x 41” high	Yes
Weight	200 lbs	200 lbs	58 lbs	135 lbs	200 lbs	--

Safety and Effectiveness:	The indications for use are based upon the indications for use for predicate systems. Technologically, the JOULE ProFractional System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the JOULE ProFractional System are comparable to the predicate devices.
Conclusion:	JOULE ProFractional System shares similar indications for use, design features, and similar functional features as, and therefore is substantially equivalent to the currently marketed predicate devices.