December 19, 2025

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

Re: K251077
Trade/Device Name: JOULE 1064nm System and Accessories
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 25, 2025
Received: November 25, 2025

Dear Jay 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 (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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

JESSICA CARR -S

Jessica Carr, PhD
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)*
K251077

Device Name
Joule 1064nm System and Accessories

Indications for Use *(Describe)*

The 1064 Laser Systems and Accessories are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications.

Dermatology:
Coagulation and hemostasis of benign vascular lesions such as, but not limited to port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.

When used with the specified treatment protocol, it is also intended for histological clearance of biopsy-confirmed nodular or superficial basal cell carcinoma (BCC) located on the trunk, in individuals with Fitzpatrick skin types I-II. The rate of recurrence after this procedure is not known.

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.

Removal of unwanted hair, for the stable long term, or permanent hair reduction through selective targeting of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB). The 1064 Laser System and Accessories are indicated for use on all skin types (Fitzpatrick I-Vl), including tanned skin.

The 1064 Laser Systems and Accessories are indicated for the treatment of facial wrinkles.

Surgical Applications:
Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

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

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:	December 18, 2025
Device Trade Name:	Joule 1064nm System and Accessories
Common Name:	Powered Laser Surgical Instrument
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology, 21 CFR 878.4810
Classification Product Code:	GEX
Regulatory Class:	Class II
Legally Marketed Predicate/Reference Devices:	K023881 (Primary Predicate), Sciton Profile 1064 Laser System K122567 (Secondary Predicate), Joule 810/940/980 Multi-platform System, Sciton, Inc. K063748 (Reference device), Thermomed 1.8, Thermosurgery Technologies, Inc.
Description of the JOULE 1064nm System:	The JOULE 1064nm Laser System is a device which delivers laser energy at a wavelength of 1064 nm. It consists of a console and laser delivery accessories. It uses focusing optics to deliver optical energy to the treatment site. The control console houses the power supply, cooling system, articulated arm delivery system with a treatment handpiece. The user activates laser emission by means of a footswitch.
Indications for Use:	The 1064 Laser Systems and Accessories are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laproscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, pulmonary/thoracic surgery and urology for surgical and aesthetic applications. Dermatology: Coagulation and hemostasis of benign vascular lesions such as, but not limited to port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. When used with the specified treatment protocol, it is also intended for histological clearance of biopsy-confirmed nodular or superficial basal cell carcinoma (BCC) located on the trunk, in individuals with Fitzpatrick skin types I-II. The rate of

recurrence after this procedure is not known.

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The 1064 Laser Systems and Accessories are indicated for the treatment of facial wrinkles.

Surgical Applications:

Incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laparoscopy, gastroenterology, general surgery, head and neck/otorhinolaryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) and urology.

Technological Characteristics:

	JOULE 1064nm Laser System		
Specification	**This Application**	**Primary Predicate Device**	**Secondary Predicate Device**
	JOULE 1064nm System	**Profile 1064 Laser System**	**Joule 810/940/980 Multi-Platform System**
Ref. 510(k)	K251077	K023881	K122567
Energy source	Nd:Yag	Nd:Yag	Diode laser
Wavelength	1064 nm	1064 nm	810, 940 & 980 nm
Spot Size	0.5 - 15 mm	0.5 - 15 mm	0.6 - 12 mm
Pulse Repetition Rate	≤ 60 Hz	≤ 15 Hz	≤ 200 Hz
Pulse Duration	0.1 - 200 msec	0.1 - 300 msec	≤ 2500 msec
Energy	Up to 140 J/cm^2	Up to 400 J/cm^2	Up to 120 J/cm^2
Utilities	230 VAC, 50/60 Hz, 1Φ	230 VAC, 50/60 Hz, 1Φ	230 VAC, 50/60 Hz, 1Φ
Power	120 W	100 W	100 W
Aiming Beam	Red	Red	Red
Delivery System	Arm and Handpiece	Arm and Handpiece	Fiber optic with handpiece
Emission Control	Footswitch	Footswitch	Footswitch
Display Screen	Yes	Yes	Yes
Cooling System	Water to Air	Water to Air	Water to Air
Control System	Microprocessor	Microprocessor	Microprocessor
Weight	200 lbs	200 lbs	200 lbs
Dimensions	43" x 32" x 15"	43" x 32" x 15"	15" x 32" x 43" high

The JOULE 1064nm System shares similar technological characteristics within the range of the predicate devices (including frequency and delivery systems, power supply, cooling and control system, power output, spot size, repetition rate, and pulse duration)

Performance Testing – Bench:

The safety and efficacy of the Joule 1064nm System were established by a series of performance tests; lab performance tests, design validation and software verification and validation. Sciton conducted bench testing to ensure that the Joule 1064nm System operates safely and within predefined design specifications.

1. Biocompatibility testing
   The patient-contacting component of the subject device in its final finished form remains unchanged from that of the primary predicate device in formulation, processing, sterilization, geometry, and body contact/clinical use

2. Electrical safety and electromagnetic compatibility (EMC) testing
   Electrical safety, EMC, device related electrical safety for higher frequency and usability tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:
   - IEC 60601-1 Medical Electrical equipment Part1: General requirements for basic safety and essential performance
   - IEC 60601-1-2 EMC testing- General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and Tests
   - IEC 60601-1-6 Medical electrical equipment -Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
   - IEC 60601-2-22 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
   - IEC 60825-1 Safety of laser products - Part 1: Equipment classification and requirements

3. Software verification and validation testing
   Software was designed and developed according to a software development process and was verified and validated in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The collective results of the non-clinical testing demonstrate that the Joule 1064nm System meets the established specifications necessary for consistent performance during its intended use.

Performance Testing – Clinical:

The effectiveness of the device in histological clearance of BCC was assessed in a prospective study at two sites. The study included 70 superficial and nodular BCC that were low risk based on subtype, body site, and size, and for which Mohs was not indicated. All BCC were previously biopsied for confirmation of diagnosis and subtype.

Each BCC was marked with a 5 mm margin of visibly clear skin, and the laser was applied using one of two protocols (low fluence/high pass number, or high fluence/low pass number) until the tissue was observed to change color to lilac-gray. Patients returned for evaluation after healing. If residual BCC was identified by physical exam and dermoscopy, an additional laser procedure was performed, for up to three laser procedures total.

When clinical (visible) clearance was observed on physical examination and dermoscopy, the BCC site was excised and assessed for residual BCC histologically using Mohs technique. Responders were defined as having histological clearance 3 months after the last treatment.

All BCC were clinically clear (no visible BCC remaining) at the time of excision. Histological evaluation of the clinically cleared BCC demonstrated that histological clearance rates (responder rates) after 1, 2, or 3 procedures, were 63%, 79%, and 87%, respectively.

Subgroup analyses showed lower response rates for Fitzpatrick III patients, BCC on the arms, and with use of the high fluence/lower pass number protocol. Insufficient data was available to evaluate response on the legs. The data supports safety and effectiveness of the device when intended to provide histological clearance of superficial or nodular BCC on the trunk that are not appropriate for Mohs, in Fitzpatrick I-II individuals, with the low fluence/higher pass number protocol (in which surface temperature is maintained between

52-54°C for 80 seconds). After three procedures, histological clearance for this subset (based on 28 BCC), was 93%. This clearance rate is comparable to that demonstrated by reference device K063748 when used for BCC.

The study did not assess long term follow up, as all BCC were excised for histological assessment for study purposes. The rate of recurrence is therefore not known.

Conclusions:

The Joule 1064nm System is similar to the predicate devices with respect to principles of operation, technological characteristics, as well as performance characteristics. Results of design validation and verification activities, i.e., testing to designated standards and performance testing of the device has demonstrated substantial equivalence of the subject device to the predicate devices in terms of safety and effectiveness for the indications for use.