April 15, 2022

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

Re: K213350
Trade/Device Name: mJOULE 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: March 14, 2022
Received: March 17, 2022

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 (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)*
K213350

Device Name
mJOULE System and Accessories

Indications for Use *(Describe)*
The mJoule 1064 laser systems and accessories is intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastic, 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, venous 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. 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.
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 pseudo folliculitis barbae (PFB). The mJoule 1064 laser system and accessories is indicated for use on all skin types (Fitzpatrick I-Vl), including tanned skin.
The mJoule 1064 laser system and accessories is indicated for the treatment of facial wrinkles.
Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).
Treatment of Aphthous Ulcers.
Excision and Vaporization of Herpes Simplex I and II.
Laser assisted uvulopalatoplasty (LAUP).
Laser assisted lipolysis.
Treatment of mild to moderate inflammatory acne vulgaris.
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, oculoplastic, 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.

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510(k) Summary
K213350

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:	October 4, 2021
Device Trade Name:	mJOULE System
Common Name:	Laser Powered Surgical Device (and Accessories)
Classification Name:	Laser Surgical Instrument, 21 CFR 878.4810.
Classification Product Code:	GEX
Legally Marketed Predicate Device:	K191842 Quanta System Discovery Pico Family K182088 Fotona Dynamis Pro Family K023881 Sciton Profile 1064 Laser System and Accessories
Description of the mJOULE 1064 nm Laser System:	The mJOULE 1064nm Laser System 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, fiber arm delivery system with a handpiece. The user activates laser emission by means of a footswitch.
Indications for Use:	The mJOULE 1064 laser systems and accessories is intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastic, 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, venous 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. 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. 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 pseudo folliculitis barbae (PFB). The mJOULE 1064 laser system and accessories is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. The mJOULE 1064 laser system and accessories is indicated for the treatment of facial wrinkles. Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.). Treatment of Aphthous Ulcers. Excision and Vaporization of Herpes Simplex I and II. Laser assisted uvulopalatoplasty (LAUP).

	Laser assisted lipolysis. Treatment of mild to moderate inflammatory acne vulgaris. 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, oculoplastic, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g., menorrhagia) and urology.
Technological Characteristics:	The mJOULE 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.

Comparative representation of the Quanta System Discovery Pico Family (K191842), the Fotona Dynamis Pro Family (K182088), the Sciton Profile 1064 Laser System and Accessories (K023881) which are the predicate for the newly submitted device (mJOULE 1064 Laser system and Accessories)

Specification	**Predicate Device**	**Primary Predicate Device**	**Predicate Device**	**This Application**	**Substantially Equivalent**
510(k) Number	**K191842**	**K182088**	**K023881**	**N/A**	--
Product	**Quanta System Discovery Pico Family**	**Fotona Dynamis Pro Family**	**Sciton Profile 1064 Laser System and Accessories**	**mJOULE 1064 Laser System and Accessories**	**--**
Regulation	GEX, 21 CFR 878-4810	GEX, 21 CFR 878-4810	GEX, 21 CFR 878-4810	GEX, 21 CFR 878-4810	Yes
CDRH Laser Class	Class 4	Class 4	Class 4	Class 4	Yes
Energy Source	Nd: YAG, and Ruby	Nd: YAG	Nd: YAG	Nd: YAG	Yes
Device Class	II	II	II	II	Yes
Laser Wavelength (nm)	1064	1064	1064	1064	Yes
Maximum Repetition Rate	Up to 10 Hz	Up to 100 Hz	15 Hz	20 Hz	Yes
Pulse Duration	0.3 – 50 ms	0.1 – 50 ms	0.1 – 300 ms	0.1 – 300 ms	Yes
Spot Size	2 to 8 mm	3 – 9 mm	0.5 – 15 mm	0.5 – 15 mm	Yes
Fluence	Up to 300 joules/cm^2	Up to 300 joules/cm^2	Up to 400 joules/cm^2	Up to 400 joules/cm^2	Yes
Utilities	200-240 VAC, 50/60 Hz	100-240 VAC	230 VAC, 50/60 Hz	230 VAC, 50/60 Hz	Yes
Aiming Beam	650 nm (red)	635 nm/650 nm (red) or 520-535 nm (green); <1 mW	650 nm (red); <1 mW	650 nm (red); <1 mW	Yes
Delivery System	Fiber/Arm	Fiber	Arm	Fiber/Arm	Yes
Handpiece	Single spot or scanner	Single spot or scanner	Single spot or scanner	Single spot or scanner	Yes
Power (Watts)	N/A	Up to 80 W	50 W	50 W	Yes
Cooling System	Water to Air	Water to Air	Water to Air	Water to Air	Yes
Control System	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	Yes
Safety	Safety Eyewear and Remote Interlock Connector	Safety Eyewear and Remote Interlock Connector	Safety Eyewear and Remote Interlock Connector	Safety Eyewear and Remote Interlock Connector	Yes
Console Dimension	20.8” x 41” x 42”	N/A	14” x 21” x 41”	12” x 15” x 43”	Yes
User Interface	Touch screen control	Touch screen control	Touch screen control	Touch screen control	Yes
Indications for Use	*See section 1.1*	*See section 1.2*	*See section 1.3*	*See section 1.4*	Yes
Note: The IFU for K191842 and K182088 mentioned in this table is not the complete IFU but only the IFU related to the YAG 1064 nm laser.					

Section 1.1 (K191842)

Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin.
Photocoagulation and hemostasis of benign pigmented and benign vascular lesions, such as, but not limited to port wine stains, hemaongiomae, warts, telangiectasia, rosacea, Venus Lake, leg veins and Spider veins.
Coagulation and hemostasis of soft tissue.
Treatment of wrinkles.
Treatment of mild to moderate inflammatory acne vulgaris.

Section 1.2 (K182088)

The Dynamic Nd: YAG laser is intended for incision, ablation, vaporization coagulation and hemostasis of vascular lesions and soft tissue in various dermatological and surgical areas, and for permanent reduction of unwanted hair in Fitzpatrick skin types I - VI.
Surgical incision, excision, vaporization, ablation and coagulation of soft tissue. All soft tissue is included, striated and smooth tissue, muscle, cartilage, meniscus, mucous membrane, lymph vessels and nodes, organs and glands, fibroma removal, frenectomy and frenotomy.
Treatment of Aphthous Ulcers.
Excision and Vaporization of Herpes Simplex I and II.
Laser assisted uvulopalatoplasty (LAUP).
Laser assisted lipolysis.
Removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The laser is indicated for all skin types, Fitzpatrick I-VI, including tanned skin. Permanent hair reduction is defined as the long-term, stable reduction in the number if hair regrowing when measured at 6, 9 and 12 months after the completion of a treatment regime.
Treatment of wrinkles.
Treatment of wrinkles with S11 scanner.
Treatment of mild to moderate inflammatory acne vulgaris.
Photocoagulation and hemostasis of pigmented and vascular lesions, such as, but not limited to, port wine stains, hemangioma, warts, telangiectasia, rosacea, venous lake, leg veins and spider veins.
Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including: Matrixectomy, Radical nail excision, Periungual and subungual warts, Plantar warts, Neuromas.
Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.)
Endo Venous Laser Therapy of superficial incompetent tributary veins associated with varicose veins and varicosities.

Section 1.3 (K023881)

The 1064 laser system and accessories are intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastic, 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), cafe 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. 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.

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 pseudo folliculitis barbae (PFB). The Profile 1064 laser system and accessories is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The Profile 1064 laser system and accessories is indicated for the treatment of facial wrinkles.

The intended use of the contact cooling system in the Profile handpiece is to provide cooling of the skin prior to, during and after laser treatment, for the epidermal protection and reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

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, oculoplastic, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g., menorrhagia) and urology.

Section 1.4 (this application)

The mJOULE 1064 laser systems and accessories is intended for use in the medical specialties of general and plastic surgery, dermatology, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastic, 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, venous 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. 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.

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 pseudo folliculitis barbae (PFB). The mJOULE 1064 laser system and accessories is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The mJOULE 1064 laser system and accessories is indicated for the treatment of facial wrinkles.

Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes Trichophyton rubrum and T. mentagrophytes, and/or yeasts Candida albicans, etc.).
Treatment of Aphthous Ulcers.
Excision and Vaporization of Herpes Simplex I and II.
Laser assisted uvulopalatoplasty (LAUP).
Laser assisted lipolysis.
Treatment of mild to moderate inflammatory acne vulgaris.

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, oculoplastic, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g., menorrhagia) and urology.

Safety and Effectiveness	The indications for use are based upon the indications for use for predicate systems. Technologically, the mJOULE System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the mJOULE System is comparable to the predicate devices.
Summary of Non-clinical Tests:	Performance: FDA recognized consensus standards were utilized to evaluate the mJOULE system for non-clinical performance. These included electrical, mechanic EMC testing, usability and essential performance of the mJOULE system. • IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 applicable for the general requirements concerning basic safety and essential performance that are applicable to medical electrical equipment. Examples of tests performed on the mJOULE system based upon this standard are power input, humidity, durability of markings, leakage current, dielectric strength, excessive temperature, push & impact tests, etc. • IEC 60601-1-2: 2014 indicates the conformity of the mJOULE system to the basic safety and essential performance of medical equipment (ME) in the presence of electromagnetic disturbance and for electromagnetic emission of ME systems. Examples of the tests performed are electrostatic discharge immunity test, electromagnetic field immunity, transient immunity, power frequency magnetic field immunity, voltage dips/interruptions immunity tests, etc.

- IEC 60601-1-6: 2010, AMD:2013 indicates the usability of mJOULE system and its associated accessories.
  Examples of evaluations performed are usability of engineering principles, hazards related to usability, user interface, medical benefits versus risks, etc.

- IEC 60601-2-22: 2007(Third edition) +A1:2012 for use in conjunction with IEC 60601-1:2005 (Third edition) + A1:2012 indicates the conformity of mJOULE system with the particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnose laser equipment.
  Examples of test performed are: Interruption of power supply, indication of laser output, indications of parameters relevant to safety and emergency stop.

- IEC 60825-1: 2014 (Third edition) applicable for the safety of mJOULE system and its delivery accessories.
  An Examples of test performed is: Determination of accessible emission levels.

Biocompatibility: The biocompatibility is not applicable for mJOULE ClearSilk delivery system since there is no tissue contacting component for its indications. ClearV handpiece application in treating the vascular lesions is however a tissue contacting component in the mJOULE system.
The skin touching surface of the ClearV handpiece for the vascular lesion treatment is a gold framed sapphire window spacer that provide cooling to the skin. The biocompatibility evaluation of the sapphire window and the gold frame in the ClearV handpiece was conducted in accordance with the international standard ISO-10993-1 “Biological evaluation of medical devices-part1: evaluation and testing within a risk management process.” As identified by FDA (See attachment VI).
Software: Software verification and validation testing documents are provided in attachment VII of the document as recommended by “Guidance for the content of premarket submissions for software contained in medical devices.” Considered as “Moderate” level of concern. All the items in the software risk analysis, software development procedure, cybersecurity risk analysis, software requirement specification, software design documentation, software test plan and traceability analysis met the requirements.
Sterility: The mJOULE system has no component or accessory that is sold sterile.
Shelf-life: Shelf-life is not applicable for mJOULE system because of low likelihood of time-dependent product degradation.

Conclusion: The conclusions drawn from the non-clinical tests demonstrate that the mJOULE system is safe and effective, and performs as well as or better than the legally marketed device predicate.