July 19, 2022

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

Re: K213761
Trade/Device Name: Joule diVa 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: June 8, 2022
Received: June 9, 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,

Jianting Wang
Acting 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)*
K213761

Device Name
JOULE diVa Laser Device

Indications for Use *(Describe)*

The JOULE diVa Laser Device with its accessories is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, ENT, Gynecology, General Surgery, Podiatry, and Ophthalmology (skin around the eyes).

The JOULE diVa Laser System, when used with its micro beam handpieces, is intended for use in Dermatological procedures and Skin resurfacing procedures.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K213761 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: | July 16, 2022 |
| Device Trade Name: | JOULE diVa Laser Device |
| 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<br>K060033 Profile Multi-Platform System<br>K210634 MCL 31 Dermablate System |
| Description of JOULE diVa Laser Device: | The JOULE diVa Laser Device consists of a console and laser deliver 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 and/or fiber optic arm delivery system with a handpiece. The user activates laser emission by means of a footswitch. |
| Intended Use: | The JOULE diVa Laser Device with its accessories is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, ENT, Gynecology, General Surgery, Podiatry, and Ophthalmology (skin around the eyes).<br><br>The JOULE diVa Laser System, when used with its micro beam handpieces, is intended for use in Dermatological procedures and Skin resurfacing procedures. |
| Technological Characteristics: | The JOULE diVa Laser Device 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. |

| JOULE diVa Laser Device | | | | | |
|---|---|---|---|---|---|
| **Specification** | **Predicate Device** | **Predicate Device** | **Predicate Device** | **This Application** | **Similar** |
| Ref. 510(k) | **K101916** | **K060033** | **K210634** | **K213761** | -- |
| Product | **Joule Multi-Platform System**<br>**1470 nm Laser System** | **Joule Multi-Platform System**<br>**2940 nm Laser System** | **MCL 31 Dermablate System** | **Joule diVa Laser Device** | -- |
| Indications for Use | The JOULE 1470 nm Multi-Platform Systems and delivery accessories are intended for delivery of laser light to soft tissue for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue. The device is indicated for the treatment of reflux of the saphenous veins associated with varicose veins and varicosities.<br>The JOULE 14 70 nm Multi-Platform Systems with Profractional handpiece and delivery system is intended for use in dermatological procedures requiring skin resurfacing and coagulation of soft tissue. | General Surgery<br>The Er: YAG is intended for the surgical incision/excision, vaporization and coagulation of soft tissue during any general surgery application where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors, tissue ablation and/or vessel coagulation.<br>Gynecology:<br>Indications include cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts and condyloma. | The MCL 31 Dermablate system with its accessories is indicated for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, Oral Surgery, ENT, Gynecology, General Surgery, Podiatry, and Ophthalmology (skin around the eyes).<br>The MCL 31 Dermablate System, when used with its micro beam handpieces, is intended for use in Dermatological procedures and Skin resurfacing procedures. | The JOULE diVa Laser Device with its accessories is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in Dermatology, Plastic Surgery, ENT, Gynecology, General Surgery, Podiatry, and Ophthalmology (skin around the eyes).<br>The JOULE diVa Laser System, when used with its micro beam handpieces, is intended for use in Dermatological procedures and Skin resurfacing procedures. | Yes |
| CDRH Laser Class | Class 4 | Class 4 | Class 4 | Class 4 | Yes |
| Energy Source | Diode Laser, CW, pulsed | Erbium YAG Laser | Erbium YAG Laser | Diode Laser, CW, pulsed<br>Erbium YAG Laser | Yes |
| Laser Wavelength | 1470 nm | 2940 nm | 2940 nm | 1470 nm and 2940 nm | Yes |
| Pulse Duration | Up to 100 sec | 100 µs-1000 ms | 100 - 1000 µs | Up to 1000 ms | Yes |
| Power | Up to 100 W | 100W | -- | Up to 100 W | Yes |
| Pulse Repetition Rate | -- | 5-60 Hz | 20 Hz | 5-60 Hz | Yes |
| Energy per Pulse | -- | 0.2-7.0 Joules | 2.5 Joules | 0.2-7.0 Joule | Yes |
| Display Screen | Yes | Yes | Yes | Yes | Yes |
| Utilities | 230 VAC/30A, 50/60 Hz | 220 VAC/ 50/60 Hz/ 1ϕ | -- | 230 VAC/30A, 50/60 Hz | Yes |
| Aiming Beam | Red/Green | Red | Red | Red/Green | Yes |
| Delivery System | Articulated Arm or Fiber Optic | Articulated Arm or Fiber optic | Articulated Arm | Articulated Arm or Fiber optic | 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 Dimensions | 14” x 21” x 41” high | 14” x 21” x 41” high | 11” x 23” x 37” high | 14” x 21” x 41” high | Yes |

| | | | | | |
|---|---|---|---|---|---|
| Weight | 200 lbs | 200 lbs | 165 lbs | 200 lbs | Yes |
| **Handpiece** | | | | | |
| Photos |  | |  |  | |
| Spot Size | 430 µm | | 425 µm & 600 µm | 450 µm | Yes |
| Energy per Pulse | < 70 mJ/microbeam | | -- | < 70 mJ/microbeam | Yes |
| Fluence | Up to 48 J/cm$^2$ | | Up to 35 J/cm² | Up to 48 J/cm$^2$ | Yes |
| Pulse Duration | Up to 1000 ms | | -- | Up to 1000 ms | Yes |
| Distance Indicator | Stainless steel spacer | | Dilator | Strengthened quartz dilator | Yes |
| Aiming Beam | 630 – 680 nm <2.5 mW | | 630 – 680 nm <2.5 mW | 630 – 680 nm <2.5 mW | Yes |
| Output Mode | Fractional pulsed mode | | Fractional pulsed mode | Fractional pulsed mode | Yes |
| Laser Media | Flashlamp pumped solid state laser and laser diode | | Flashlamp pumped solid state laser and laser diode | Flashlamp pumped solid state laser and laser diode | Yes |

Safety and Effectiveness: The indications for use are based upon the indications for use for predicate systems. Technologically, the JOULE diVa Laser Device is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the JOULE diVa Laser Device are comparable to the predicate devices.

**Summary of Non-clinical Tests:**

Performance: FDA recognized consensus standards were utilized to evaluate the JOULE system for non-clinical performance. These included electrical, mechanical, EMC testing, usability and essential performance of the JOULE system.

The following information summarizes the non-clinical bench performance testing performed for the predicate devices and the subject device (Joule diVa Laser Device).

| Joule Multi-Platform System 1470 nm Laser System | Joule Multi-Platform System 2940 nm Laser System | MCL 31 Dermablate System | Joule diVa Laser Device |
|---|---|---|---|
| IEC 60601-1-4 | IEC 60601-1-4 | - | - |
| IEC 60601-2-22 | IEC 60601-2-22 | IEC 60601-2-22 | IEC 60601-2-22: 2007 (3d edition) + A1:2012 |
| IEC 60601-1 | IEC 60601-1 | IEC 60601-1 | IEC 60601-1: 2005 |
| IEC 60601-1-2 | IEC 60601-1-2 | IEC 60601-1-2 | IEC 60601-1-2 (Ed 4.0): 2014 |
| IEC 60601-1-6 | - | - | IEC 60601-1-6: 2010 AMD1:2013 |

- IEC 60601-2-22: 2007 (3d edition) +A1:2012 indicates the conformity of JOULE 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 60601-1:2005 is applicable for the general requirements concerning basic safety and essential performance that are applicable to medical electrical equipment.
  Examples of tests performed on the JOULE 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 (Ed 4.0): 2014 indicates the conformity of the JOULE 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 AMD1:2013 indicates the usability of JOULE 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.

Biocompatibility: The biocompatibility of the patient-contacting component of the JOULE diVa delivery system (HEREAUS QUARTZ GLASS TUBE HLQ 200 V8) were confirmed in testing by Nelsons Lab with passing cytotoxicity, irritation and sensitivity test results.
The cytotoxicity test was conducted in accordance with ISO 10993-5 and USP guidelines.
The Irritation test result met the requirements of the ISO 10993-10 and ISO 10993-23 guidelines.
The sensitization test results met the requirements of the ISO 10993-10 guidelines.

Software: Software verification and validation testing documents were provided as recommended by "Guidance for the content of premarket submissions for software contained in medical devices." 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 JOULE system has no component or accessory that is sold sterile.

Shelf-life: Shelf-life is not applicable for JOULE system because of low likelihood of time-dependent product degradation.

Conclusion: The conclusions drawn from the non-clinical tests demonstrate that the JOULE diVa Laser device is as safe as the legally marketed device (predicate).

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| Conclusion: | JOULE diVa Laser Device shares similar indications for use, design features, and similar functional features, and is therefore substantially equivalent to the currently marketed predicate devices. |