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

March 6, 2019

Re: K182173
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: February 6, 2019
Received: February 8, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

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
Indications for Use

510(k) Number (if known)
K182173

Device Name
Joule 1927nm Laser System

Indications for Use (Describe)
Joule 1927nm Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

Type of Use (Select one or both, as applicable)

- [X] 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: March 6, 2019
Device Trade Name: JOULE 1927nm Laser 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: K130193: Solta FraxelDUAL
K171009: Lutronic LAEMD Laser System

Description of the JOULE 1927nm Laser System
The JOULE 1927nm Laser System consists of a console and laser deliver accessories. It uses focusing optics to deliver optical energy to the treatment site.

Technological Characteristics:

Intended Use:
The JOULE 1927nm Laser System with its accessories is intended for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

The JOULE 1927nm Laser 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.
<table>
<thead>
<tr>
<th>Specification</th>
<th>FraxelDUAL</th>
<th>LASEMD Laser System</th>
<th>JOULE 1927 nm</th>
<th>Substantially Equivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for Use</td>
<td>The Fraxel 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratoses, and treatment of pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).</td>
<td>The LASEMD Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratoses, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).</td>
<td>JOULE 1927 nm Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratoses, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).</td>
<td>Yes</td>
</tr>
</tbody>
</table>

| Ref. 510(k)         | K130193    | K171009            | N/A           | --                        |
| CDRH Laser Class    | Class 4    | Class 4            | Class 4       | Yes                       |
| Laser Type          | Thulium Laser                     | Thulium Laser | Thulium Laser      | Yes                       |
| Energy Source       | 1927 nm    | 1927 nm            | 1927 nm       | Yes                       |
| Spot Size           | 256 – 620 μm | 100 - 200 μm      | 100 – 620 μm  | Yes                       |
| Maximum Tip Width   | 7 and 15 mm | 10 mm             | 15 mm         | Yes                       |
| Wavelength          | 1927 nm    | 1927 nm            | 1927 nm       | Yes                       |
| Pulse Repetition Rate | 0 – 3 kHz     | 43.5 – 307.7 Hz   | 0 – 3 kHz     | Yes                       |
| Pulse Duration      | Up to 10 ms | Up to 20 ms       | Up to 20 ms   | Yes                       |
| Energy              | Up to 20 mJ | Up to 20 mJ       | Up to 20 mJ   | Yes                       |
| Utilities           | 120-240 VAC,50/60 Hz | 100-240 VAC, 50/60 Hz | 200-240 VAC/25A, 50/60 Hz | Yes |
| Power               | 12 W (1927 nm) | 5 W (1927 nm)     | 12 W (1927 nm) | Yes                       |
| Aiming Beam         | Red         | Red                | Red           | Yes                       |
| Delivery System     | Fiber optic | Fiber and Handpiece | Articulated Arm or Fiber optic | Yes |
| Emission Control    | Footswitch  | Footswitch         | Footswitch    | Yes                       |
| Display Screen      | Yes         | Yes                | Yes           | Yes                       |
| Cooling System      | Air to Air  | Air to Air         | Water to Air  | Yes                       |
| Control System      | Microprocessor | Microprocessor | Microprocessor | Yes                       |
| Energy Monitor      | 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  | 19” x 18” x 18” high | 16” x 10” x 13” high | 14” x 21” x 41” high | Yes |
| Weight              | 55 lbs      | 73 lbs             | 200 lbs       | --                        |
| Non-Clinical Performance Data | Electrical safety and electromagnetic compatibility testing was performed per standards IEC 60601-1: 2012 reprint, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-2-22:2007 and IEC 60825-1:2014. Software verification and validation was successfully performed. Patient contacting component was tested for biocompatibility per ISO 10993-1 and was determined to be biocompatible. |
| Safety and Effectiveness: | The indications for use are based upon the indications for use for predicate systems. Technologically, the JOULE 1927nm Laser System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the JOULE 1927nm Laser System is comparable to the predicate devices. |
| Conclusion: | JOULE 1927nm Laser System shares similar indications for use, design features, and similar functional features as, and therefore is substantially equivalent to the currently marketed predicate devices. |