April 23, 2024

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

Re: K222958
Trade/Device Name: mJOULE RF System and Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 22, 2024
Received: March 25, 2024

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.04.23 08:18:06 -04'00'

Mark Trumbore, Ph.D.
Acting Division 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)*
K222958

Device Name
mJoule RF System

Indications for Use *(Describe)*
The mJoule RF System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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:	April 19, 2024
Device Trade Name:	mJOULE RF System
Common Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories, 21 CFR 878.4400
Classification Product Code:	GEI
Legally Marketed Predicate Device:	K192545 Potenza
Description of the mJOULE RF System:	The mJOULE RF System consists of console and radio frequency delivery accessories. The control console houses the power supply, cooling system and RF delivery system. The treatment parameters are entered via a touchscreen on the console. The user activates RF emission by means of a footswitch.
Indications for Use:	The mJOULE RF system is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Technological Characteristics:	The mJOULE System shares the same indications for use. Predicate Comparison of this submission, shares similar design features (including frequency and delivery systems, power supply, cooling and control system), functional features (including power output and needle array size), and is therefore substantially equivalent to the above legally marketed predicate device.

Comparative representation of Potenza (K192545), which is the predicate for the subject device, mJOULE RF System (K222958).

Specification	Predicate Device	This Application
510(k) Number	K192545	K222958
Product	Potenza	mJOULE RF System
Regulation	GEI, 21 CFR 878.4400	GEI, 21 CFR 878.4400
Device Class	II	II
Intended Use	The POTENZA is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.	mJOULE RF System is intended for use in in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
Frequency	1MHz, 2MHz	1MHz
Needle Array Size	7x7, 5x5, 4x4, 1	7x7, 6x6
Needle Array Pitch	1.4 mm, 2 mm	1.4 mm, 1.7 mm
Needle Exposed Length	0.4 mm	0.4 mm
Needle Depth	0.5 – 4.0 mm	0.5 – 4.0 mm
Needle Polarity	Bipolar	Bipolar
Needle Diameter	0.2 mm	0.2 mm
Treatment Time	10 – 500 ms	10 – 600 ms
Power Max	50 W	50 W
Power per Needle	1.02 W for 7x7 array	1.02 W for 7x7 & 6x6 array
Sterilization	EO	EO
Power Source (Active Accessory)	100 - 240 VAC, 50/60 Hz	100 - 240 VAC, 50/60 Hz
Electrode - Single Use (Yes/No)	Yes	Yes
Control System	Microprocessor	Microprocessor
Energy Monitor	Display Indicates Energy Delivered to Tissue	Display Indicates Energy Delivered to Tissue
Safety	NA	Safety Eyewear and Remote Interlock Connector
Safety Compliance Standards	IEC 60601-1, IEC 60601-1-2, IEC 60101-2-2, IEC 60601-1-6	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-2, IEC 60601-1-6
Console Dimension	20” x 14” x 12”	12” x 15” x 43”
User Interface	Touch screen control	Touch screen control

Performance Testing – Bench:

The safety and efficacy of the mJoule RF 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 mJoule RF System operates safely and within predefined design specifications.

1. Tested parameters include:
   - Frequency: Bipolar at 1MHz
   - Power measurements
   - Energy per pin and total energy
   - Impedance measurement accuracy and range
   - Safety test of various warnings / failsafe mechanisms
   - Needle depth
   - Motor speed level

2. Biocompatibility testing
   The biocompatibility tests were performed according to ISO 10993 standards for acute systemic toxicity, cytotoxicity, irritation, sensitization, and pyrogenicity assessment of mJoule RF device as recommended in ISO 10993-1 and FDA's guidance document.

3. Sterilization testing
   The sterilization of single use disposable tips was tested to ensure the sterility assurance level (SAL) of at least 10^{-6}.

4. Electrical safety and electromagnetic compatibility (EMC)
   Electrical safety, EMC, device related electrical safety for higher frequency and usability were conducted on the mJoule RFMN system according to the following consensus 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 60601-2-2 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

5. Software verification and validation testing
   Software verification and validation testing was conducted in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for the subject device.

Performance Testing – Thermal Testing:

Thermal testing is conducted on ex vivo porcine tissue in accordance with FDA's Guidance for Industry and FDA Staff: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, March 9, 2020 to quantitatively determine the depth, height and width of thermal coagulative zones. It is concluded from this study that coagulation zones are created below the surface of the tissue that are proportional to the amount of energy delivered to the tissue. The ex-vivo study results show that the RF microneedling tips are safe for use and effective in achieving the specified indications of dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Safety and Effectiveness:

The mJOULE RF System is similar to predicate device 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 device in terms of safety and effectiveness for requested intended use.

Conclusion:	The mJOULE RF System shares similar indications for use, design features, and similar functional features as, and therefore is substantially equivalent to the currently marketed predicate device. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns.