Jul1y 20, 2021

LUVO Medical Technologies, Inc.
Mr. Gregory Berzak
Director of Regulatory Affairs and Quality Compliance
125 Fleming Drive
Cambridge, Ontario N1T 2B8
Canada

Re: K210129
Trade/Device Name: RF Thermal System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX
Dated: June 10, 2021
Received: June 22, 2021

Dear Mr. Berzak:

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,

Long Chen, Ph.D.
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)*
K210129

Device Name

Thermal RF System

Indications for Use *(Describe)*

The Thermal RF System is indicated for:

Heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation

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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510K Summary
RF Thermal System
K210129

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Applicant:	LUVO Medical Technologies, Inc.
Address:	LUVO Medical Technologies, Inc. 125 Fleming Dr Cambridge, Ontario, Canada N1T 2B8
Contact Person:	Mr. Gregory Berzak Director of Regulatory Affairs and Quality Compliance
Contact Information:	519-620-3900– phone gregoryb@clarionmedical.com
Preparation Date:	July 16, 2021
Device Trade Name:	RF Thermal System
Common Name:	Radio Frequency generator
Regulation Name:	21 CFR 878.4400, Electrical cutting and coagulation device and accessories; Massager, Vacuum, Radio Frequency Induced Heat
Product Code:	PBX - Massager, Vacuum, Radio Frequency Induced Heat
Legally Marketed Predicate:	K200241 - Tempsure
Regulatory Class:	Class II Prescription Use
Description of Thermal RF:	The Thermal RF System is a Class II Medical Device that utilizes monopolar RF energy for the purpose of elevating tissue temperature for selected medical conditions. The system is comprised of a micro-processor-controlled and user-friendly console that houses the power supply, the electronics and the user interface. It then has a handpiece that is attached to the console, and through the user interface can be selected for administering the treatment.
Indications for Use	Heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

Comparison to Predicate Device:

	Thermal RF K210129	Predicate: TempSure K200241	
Indication for Use	Heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation	Heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation	Same
Technical Specification			
Frequency (MHz)	4	4	Same
Operation Type	Monopolar	Monopolar	Same
Output Power	Up to 60W	120-300W	Similar
TRF-E Tip			
Treatment Area	0.38 cm^2	18mm	Similar
TRF-R Tip			
Treatment Area	2.54 cm^2	25mm	Similar
TRF-S tip			
Treatment Area	3.61 cm^2	30mm	Similar

Performance Data: The following performance data was provided in support of the substantial equivalence determination:

IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance.

IEC 60601-1-2 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility

IEC 60601-2-2 Test for Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

ISO 10993-1 Biological Evaluation of Medical Devices - Part 1:Evaluation and Testing Within a Risk Management Process

510K Summary
RF Thermal System
K210129

Thermal Testing was conducted on nine human subjects. The testing was conducted on three different parts of the body, the forearm, the thigh and the abdomen. Results showed that the Thermal RF system is capable of raising the temperature to 40°C and then maintain the temperate between 40°C – 44°C for 10 minutes, which meets the requirements for a therapeutic treatment.

Performance Test Summary:

The RF Thermal System completed performance testing to ensure safety and efficacy of the device.

Package Validation testing was performed successfully according to ASTM D 4169 : 2016. Assessment to national (National standard AAMI/IEC 60601-1:2005 + AMD 1:2012) and international regulations for Electrical devices was also performed successfully to Electrical Safety (IEC 60601), Electromagnetic compatibility (IEC 60601-1-2) and for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2).

The RF Thermal handpiece TIP comes into contact with the patient' skin was subject to Biocompatibility testing using the following standards to determine compliance: ISO 10993-1, ISO 10993-12, ISO 10993-5 & ISO 10993-10. The Raw material compliance to the Biocompatibility standards demonstrate compliance and that it is safe to contact skin as intended.

Additionally, mechanical performance was done by measuring the output accuracy of the TRF TIP, all results demonstrate accuracy within ±20%. Thermal therapeutic testing was also conducted for the RF Thermal System to show substantial equivalence and safety by showing the correlation between output energy and the corresponding temperature for the intended use. The quantitative data report ensures safety and effectiveness. The RF Thermal handpiece also has a temperature sensor which was tested successfully to demonstrate the device meets design specifications and performance requirements.

Conclusion:

The RF Thermal System has the same technology, principle of operation, indications for Use, and similar technical specifications as the predicate device. Performance test results also demonstrated the subject device can perform the same intended use as safely and effectively as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.