January 17, 2017

ThermiGen, L.L.C
Ms. Suzanne Cheang
Regulatory Affairs Director
3131 West Royal Lane, Suite 100
Irving, Texas 75063

Re: K173582
Trade/Device Name: Thermi Temperature Controlled Radiofrequency (RF) System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 17, 2017
Received: November 20, 2017

Dear Ms. Cheang:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Jennifer R. Stevenson -S3

For 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173582

Device Name
Thermi Temperature Controlled Radiofrequency (RF) System

Indications for Use *(Describe)*
The Thermi Temperature Controlled Radiofrequency (RF) System (generator, electrodes/hanpieces and accessories) are indicated:

- for use in dermatological and general surgical procedures for electrocoagulation and hemostasis
- to create lesions in nervous tissue

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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SECTION 6: 510(K) SUMMARY

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.87 and 807.92. Summary preparation date is November 15, 2017 [21 CFR 807.92(a)(1)].

General Information

Trade Name	ThermiX Temperature Controlled Radiofrequency (RF) System
Classification Name	21 CFR §878.4400 Electrosurgical Cutting and Coagulation and Accessories
Regulatory Class	Class II
Product Code	GEI
Submitter	ThermiGen, L.L.C. 3131 West Royal Lane Suite 100 Irving, TX 75063
Contact	Ms. Suzanne Cheang Regulatory Affairs, Director **Phone:** (214) 888-0683 **Fax:** (214) 279-0101 **Email:** scheang@thermi.com

Predicate Device

K130689	ThermiGen Symphony RF System
K171094	Thermi Reusable Non-invasive RF Electrode
K170116	Thermi Injectable RF Electrode

Indications for Use

The Thermi Temperature Controlled Radiofrequency (RF) System (generator, electrodes/handpieces and accessories) are indicated:

- for use in dermatological and general surgical procedures for electrocoagulation and hemostasis
- to create lesions in nervous tissue.

Device Description

The Thermi Temperature Controlled Radiofrequency (RF) System consists of a RF generator with integral temperature and impedance feedback, automatically adjusting energy delivery to maintain set temperature and percutaneous and transcutaneous electrodes accessories that deliver the RF to the targeted location on the patient's anatomy when use with Thermi RF generator. It is operating with set temperature range between 35-90^{o} C that allows the physician to control treatment temperature to achieve the desired clinical outcome.

The Thermi RF System consist of:

1. RF Generator
2. Percutaneous electrodes
3. Disposable and re-usable transcutaneous electrodes/handpieces
4. Foot pedal
5. Power cord

Thermi RF generator produces an oscillating electric field in the antenna (electrode). The oscillating electrical field is transmitted to the surrounding soft tissue, causing heating of the tissue. A thermocouple in the electrode measures this increase in temperature and maintains a feedback loop to ensure a set point temperature in the tissue.

Technological Characteristics

The Thermi Temperature Controlled Radiofrequency System is similar with regards to indications for use, design, operation principle and technological characteristics to the predicate devices that were cleared in K130689, ThermiRF System (previously named the Symphony RF System), K170116, Thermi Injectable RF Electrode and K171094, Thermi Reusable Non-invasive RF Electrode. Results of bench testing demonstrate Thermi RF Temperature Controlled Radiofrequency System is as safe and effective as the predicate devices.

Performance Data

The Thermi Temperature Controlled Radiofrequency System is similar with regards to indications for use and technological characteristics to the predicate devices that were cleared in K130689, ThermiRF System (previously named the Symphony RF System), K170116, Thermi Injectable RF Electrode and K171094, Thermi Reusable Non-invasive RF Electrode. Results of bench testing demonstrate Thermi RF Temperature Controlled Radiofrequency System works within the device parameters ranges of the legally marketed Thermi RF System with the same indications for use.

All testing performed on the Thermi Temperature Controlled Radiofrequency System derived from the risk assessment in accordance with ISO 14971 which evaluated the safety and effectiveness of the design modification in accordance with Thermi Design & Development procedures. The test methodology and acceptance criteria were developed from within Thermi and from related standards.

A series of bench testing was identified and conducted on the subject Thermi Temperature Controlled Radiofrequency System in accordance with protocols to verify design specifications as follows. Testing inclued:

- Dimensional testing
- Functional testing
- Performance testing
- Design features confirmation
- Shelf life testing

- Biocompatibility testing
- Tensile strength
- Materials confirmation
- Thermal effect on tissue testing including muscle, liver, kidney, and porcine skin
- Software functional and performance verification
- Software Validation
- Max Output Energy

Electrical safety and essential performance testing was completed on the subject Thermi Temperature Controlled Radiofrequency System in accordance with FDA Guidance "Premarket Notification 510(k) Submission for Electrosurgical Devices for General Surgery. The following electrical safety and essential performance testing was completed:

1. IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performances.

2. IEC 60601-1-2, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – requirements and test

3. IEC 60601-1-6, Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability

4. 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.

The results of testing show that the subject Thermi Temperature Controlled Radiofrequency (RF) System, met all performance and functional testing and performed as intended; and did not raise new safety or performance questions.

Conclusions

The subject Thermi Temperature Controlled Radiofrequency System is similar with regards to indications for use, design, operation principle and technological characteristics to the predicate devices that were cleared in K130689, ThermiRF System (previously named the Symphony RF System), K170116, Thermi Injectable RF Electrode and K171094, Thermi Reusable Non-invasive RF Electrode. The results of testing demonstrate that the Thermi Temperature Controlled Radiofrequency System is safe and effective; and no new questions of safety or efficacy are raised.