DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 8, 2017

ThermiGen, L.L.C
Ms. Suzanne Cheang
Regulatory Affairs Manager
8304 Esters Boulevard Suite 890
Irving, Texas 75063

Re: K171094
Trade/Device Name: Thermi Reusable Non-invasive RF Electrode
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 10, 2017
Received: April 12, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171094

Device Name
Thermi Reusable Non-Invasive RF Electrode

Indications for Use *(Describe)*
The Thermi Reusable Non-Invasive RF Electrodes used with the Thermi RF Generator System are indicated:
- for use in dermatological 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.

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SECTION 7: 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 April 10, 2017 [21 CFR 807.92(a)(1)].

General Information

Trade Name	Thermi Reusable Non-Invasive RF Electrode
Classification Name	21 CFR §878.4400 Electrosurgical Cutting and Coagulation and Accessories
Regulatory Class	Class II
Product Code	GEI
Submitter	ThermiGen, L.L.C. 8304 Esters Blvd Suite 890 Irving, TX 75063
Contact	Suzanne Cheang Regulatory Affairs Manager **Phone:** (214) 888-068 **Fax:** (214) 279-0101 **Email:** scheang@thermi.com

Predicate Device

K130689 The Symphony RF System

Indications for Use

The Thermi Reusable Non-Invasive RF Electrodes used with the Thermi RF Generator System are indicated:

- for use in dermatological and general surgical procedures for electrocoagulation and hemostasis

Device Description

The Thermi Reusable Non-Invasive RF Electrode is a transcutaneous thermal/coagulation electrode designed to provide finely-controlled radiofrequency (RF) energy in combination with Thermi RF Generator. They are not intended to function with non-Thermi branded products.

The electrode connects to a Thermi RF Generator and requires the use of a grounding pad to complete the circuit. The Electrode delivers the RF signal from the generator to the electrode active tip. From the active tip, the RF signal triggers the tissue molecules to vibrate resulting in the formation of heat.

Technological Characteristics

The Thermi Reusable Non-Invasive RF Electrode is similar with regards to materials, intended use, principles of operation and technological characteristics to the legally marketed electrode that was cleared as part of accessories to be used with Thermi RF generator by FDA in 510(k) K130689, ThermiRF System (previously named the Symphony RF System). Results of bench testing demonstrate Thermi Reusable Non-invasive RF Electrode is as safe and effective as the legally marketed predicate device.

Modification to Existing Technology

Add new Thermi Reusable Non-Invasive RF Electrodes, 15mm (RFE-15-D) to the current legally marketed device offering, 10mm (RFE-10-D) electrode. The RFE-15-D has a 15mm diameter active tip which provides larger working surface without raising any new issues of safety and efficacy.

In addition, the Thermi Reusable Non-Invasive RF Electrodes have thinner active tip profile compared to the legally marketed electrode. The thinner active tip profile reduces the thermal mass of the electrode which facilitates the measurement of changes in temperature without any new issues raise of safety and efficacy.

Performance Data

All testing performed on the modified transcutaneous electrodes derived from the risk assessment which evaluated the safety and effectiveness of the design modification. The test methodology and acceptance criteria were developed from within Thermi and from related standards.

A series of bench testing was conducted on the modified Thermi Reusable Non-Invasive RF Electrode in accordance with protocols to verify design specifications as follows: dimensional testing, functional testing, design features, and tensile strength. The results of the verification testing shown that the modified Thermi Reusable Non-invasive RF Electrodes will function as intended when used with the Thermi RF Generator.

Electromagnetic Compatibility and Electrical Safety testing was conducted on the ThermiRF accessories and ThermiRF Generator. Compliance was demonstrated through testing to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-1-6 and IEC 60601-2-2.

The results of testing show that the modified electrode Thermi Reusable Non-Invasive RF Electrode, met all performance and functional testing and performed as intended; and did not raise new safety or performance questions.

Conclusions

The Thermi Reusable Non-Invasive RF Electrode was found to be substantially equivalent to the predicate devices in terms of technology, function and intended use. The design is similar to the legally marketed transcutaneous thermal/coagulation electrode cleared by FDA in 510(k)

K130689. No new questions of safety or efficacy are raised by the introduction of the modified transcutaneous electrode.