DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 12, 2016

Thermi
Ms. Carrie Eddings
Regulatory Manager
8304 Esters Blvd Ste 890
Irving, Texas 75063

Re: K161661
Trade/Device Name: Thermi RF Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 24, 2016
Received: June 16, 2016

Dear Ms. Eddings:

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 yours,

Christopher J. Ronk -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)*

K161661

Device Name

Thermi RF Accessories

Indications for Use *(Describe)*

The Thermi RF accessories used with the Thermi RF Generator System are indicated:

* for use in dermatological and general surgical procedures for electrocoagulation and hemostasis
* to create lesions in nervous tissue when used in combination with Thermi RF Generator.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 5: 510(k) SUMMARY

I. SUBMITTER

Thermi
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Contact Person: Ms. Carrie Eddings, BA
Regulatory Manager
Contact Telephone: 214-612-5819
Contact Email: ceddings@thermi.com
Date Prepared: May 24, 2016

II. DEVICE

Name of Device: Thermi RF Accessories
Common or Usual Name: Electrosurgical Cutting and Coagulation Device and Accessories
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)
Regulatory Class: II
Product Code: GEI

III. PREDICATE DEVICE

Thermi RF Generator and Accessories, **K130689**
NeuroTherm ElectroThermal 20S, **K033981**

IV. DEVICE DESCRIPTION

The Thermi RF Accessories (electrodes, cannula, adapter cable) are designed to provide finely-controlled radiofrequency (RF) energy in combination with the predicate device Thermi RF Generator (K130689).

V. INDICATIONS FOR USE

The Thermi RF accessories used with the Thermi RF Generator System are indicated:

* for use in dermatological and general surgical procedures for electrocoagulation and hemostasis
* to create lesions in nervous tissue when used in combination with Thermi RF Generator.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of both the subject and predicate devices are identical since the accessories currently used with the Thermi RF Generator have been manufactured by St. Jude Medical Inc. (formerly NeuroTherm) and marketed under Thermi's 510(k) clearance (K130689). St. Jude Medical Inc. will begin private labeling these devices for Thermi, and as such, Thermi is submitting this 510(k) to obtain its own clearance for these devices. There are no design or manufacturing changes, other than manufacturing location (equipment being moved from Wilmington, MA to Minnetonka, MN), and the reflective labeling changes. The Thermi RF Accessories are substantially equivalent to the NeuroTherm accessories cleared under Thermi 510(k) K130689 and NeuroTherm 510(k) K033981, in terms of indications for use and functional performance.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety

Electromagnetic Compatibility and Electrical safety testing was conducted on the Thermi Symphony RF accessories and Thermi RF Generator. Compliance was shown through testing to IEC 60601-1: 2006, IEC 60601-1-2: 2001, IEC 60601-1-4: 1996, IEC 60601-1-6: 2006 and IEC 60601-2-2: 2009.

Bench testing

Bench testing was performed on the Thermi RF Accessories to verify all design specifications (including the following): temperature measurement, tensile strength, functional testing, design features, heat shrink, active tip length, packaging, and shelf-life.

Functional and Simulated Use Verification was also completed to show that the Thermi RF Accessories when used with the Thermi RF Generator, will function as intended.

The Thermi RF accessories met all performance and functional testing and performed as intended.

VIII. CONCLUSIONS

The Thermi RF Accessories passed all electrical safety and verification testing, and no new issues of safety or efficacy were raised. The testing demonstrates the Thermi RF Accessories can be safely and effectively used with the Thermi RF Generator. The means of achieving electrocoagulation and hemostasis and creating lesions in nervous tissue in dermatological and general surgical procedures with the Thermi RF Accessories is substantially equivalent to the NeuroTherm RF Accessories for the generator.