K130689

Section 5

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 5-01-2013 [21 CFR 807.92(a)(1)].

A. Applicant Name and Address [21 CFR 807.92(a)(1)]

ThermiGen Inc.

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Southlake, TX 76092

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NOV 15 2013

B. Contact Information

ThermiGen Inc.

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Contact person: Kevin O'Brien, President

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C. Device Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name: *Symphony* RF Generator
Device Common Name: Electrosurgical Cutting and Coagulation and Accessories
Classification Name: Electrosurgical Cutting and Coagulation and Accessories 21 CFR 878.4400
Product Code: GEI
Device Classification: Class II

D. Predicate Devices [21 CFR 807.92(a)(3)]

The *Symphony* RF System and the RFE-10-D handpiece use similar technology and physical output characteristics as the following predicate devices:
K033981 Smith&Nephew *ElectroThermal* 20S
K000944 Thermage *ThermaCool* System
K082834, K102368 Ellman *Three Button Fingerswitch Handpiece*

E. Device Description [21 CFR 807.92(a)(4)]

The *Symphony RF* is a 20 watt electro-thermal radio frequency (RF) generator with integral temperature and impedance feedback. The RF generator is the Smith&Nephew RF Delivery Device, unchanged and in clinical service since Feb 25, 2004 (K033981). The Symphony RF has software changes to allow for two types of electrode/hand-pieces, (1) percutaneous (existing Smith and Nephew thermal/coagulation probes, now owned and manufactured by Neurotherm, Inc.) and (2) the new transcutaneous thermal/coagulation probe, RFE-10-D.

The *Symphony* RF generator has a user interface that displays temperature set point and actual tissue temperature, procedure time, impedance, along with system error and warning codes.

The theory of operation of RF devices: The RF generator produces an oscillating electric field in the antenna (handpiece). The oscillating electrical field is transmitted to the surrounding soft tissue, causing heating of the tissue. A thermistor intrinsic to the handpiece measures this increase in temperature and in the case of the *Symphony* RF, a feedback loop maintains a set point temperature in the tissue.

F. Device Specifications [21 CFR 807.92(a)(6)]

Comparison to the predicate K033981 *ElectroThermal 20S* demonstrates both devices have the same power, frequency, and monitoring and safety functions. Comparison to the predicate K000944 *ThermaCool* System demonstrates both devices have the same power and similar frequency, monitoring and safety functions, as well as identical indications for use.

Comparison of the handpiece RFE-10D to the predicate K082834 Ellman *Three Button Fingerswitch Handpiece* demonstrates both have the same diameter of skin contact, are monopolar, are constructed with similar materials, and have a similar temperature ranges. Both handpieces are transcutaneous in terms of operation.

The *Symphony RF* system includes
1. *Symphony RF* generator
2. Hospital-grade power cord
3. Pneumatic footswitch

The Symphony RF system requires the following accessories
1. NeuroTherm Electrosurgical Neutral Electrode (REF RDGP-S)
2. NeuroTherm RF Denervation Probes, RF Electrodes, RF cannulae for percutaneous approaches.
3. NeuroTherm RFE-10D Probe for transcutaneous approaches.

G. Indications for Use [21 CFR 807.92(a)(5)]

The *Symphony* RF System and the probes that are used with it 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 NeuroTherm (previously Smith&Nephew) thermal/coagulation probes.

H. Performance Data [21 CFR 807.92(b)(2)]

There are no applicable Guidance Documents specifically associated with this type of medical device. A recognized Consensus Standard, IEC 60601-2-2 exists for RF devices. The *Symphony* RF System has been third party tested and found to conform to IEC 60601-2-2.

The *Symphony* RF was also third party tested to the IEC 60601 (3^{rd} edition) standard, along with applicable Collateral Standards (60601-1-2, 60601-1-4 and 60601-1-6). The *Symphony RF* and RFE-10-D electrode meet all manufacturing and software specifications. No additional performance or clinical testing was conducted.

I. Conclusion [21 CFR 807.92(b)(3)]

The ThermiGen *Symphony* RF was found to be substantially equivalent to the predicate devices in terms of technology, function and intended use. The indications for use are identical to the previously cleared devices (Smith&Nephew *ElectroThermal* 20S K033981 and Thermage *ThermaCool* System K000944). We believe that there are no new questions of safety or efficacy raised by the introduction of the ThermiGen *Symphony* RF System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

ThermiGen, Inc.
Mr. Kevin O'Brien
President
401 North Carroll Avenue
Southlake, Texas 76092

November 15, 2013

Re: K130689
Trade/Device Name: Symphony RF Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 20, 2013
Received: October 22, 2013

Dear Mr. O'Brien:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4

Indications for Use

510(k) Number (if known): K130689

Device Name: ThermiGen *Symphony* RF Generator

Indications for Use:

The ThermiGen *Symphony* RF Generator System and the probes that are used with it 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 NeuroTherm (previously Smith&Nephew) thermal/coagulation probes.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300349036 Date: 2013.11.15 08:35:54 -05'00' for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number K130689