DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 31, 2015

Perseon Coporation
Dixie Toolson Sells
VP Regulatory Affairs
2188 West 2200 South
Salt lake City, UT 84119

Re: K141785
Trade/Device Name: MicroThermX (MTX)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: February 17, 2015
Received: February 19, 2015

Dear Ms. Dixie Toolson Sells:

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 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. 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 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,

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)*
K141785

Device Name

MicroThermX Microwave Ablation System

Indications for Use *(Describe)*

The MicroThermX Microwave Ablation System (MTX) delivers microwave energy for coagulation (ablation) of soft tissue. The system is not intended for use in cardiac procedures. The SynchroWave antennas may be used in open surgical procedures and in laparoscopic and percutaneous ablation procedures, using image guidance, including partial or complete ablation of non-resectable liver tumors. An optional TempSure temperature sensor may be used to monitor tissue temperatures.

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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510(k) SUMMARY

SPONSOR

Perseon Corporation
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CONTACT/ SUBMITTED BY

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DATE PREPARED

March 24, 2015

TRADE OR PROPRIETARY NAME

MicroThermX® Microwave Ablation System (MTX)

CLASSIFICATION/ NAME

Class II, (21CFR §878.4400), Electrosurgical cutting and coagulation device and accessories
Product Code- NEY

PREDICATE DEVICES

MicroThermX Microwave Ablation System (MTX-180) (K100786).

Valleylab (Covidien) Microwave Ablation Generator (K072687). (System also referred to as Vivant Medical VivaWave Microwave System - K053535) Valleylab (Covidien) VivaRing Microwave Ablation Probe (K040279.)

DEVICE DESCRIPTION

The MicroThermX® Microwave Ablation System (MTX) delivers 915 MHz microwave energy for coagulation (ablation) of soft tissue. The procedure time and power parameters are operator selected via a touchscreen monitor.
The system consists of a generator and pump attached to a mobile cart or tabletop stand, sterile disposable SynchroWave antennas with cooling circuit, and optional disposable TempSure temperature sensors.

The closed cooling circuit consists of a bag of sterile isotonic saline (not supplied by Perseon), disposable, single-use cooling circuit tubing and connectors; and fluid pathway channels within each single-use antenna. A reusable pump circulates isotonic saline through the cooling circuit.

The MTX is designed to:

- Provide repeatable ablation zone geometries for a given set of ablation parameters (based on studies conducted on non-perfused animal tissue).
- Be used in intraoperative procedures and in minimally-invasive laparoscopic or percutaneous procedures, using image guidance.
- Utilize a single SynchroWave antenna or synchronous wave alignment operation of 2 or 3 SynchroWave antennas during a single procedure to induce larger zones of ablation.
- Utilize an optional TempSure sensor to monitor the temperature of non-target tissue.

INTENDED USE

The MTX delivers microwave energy for coagulation (ablation) of soft tissue. The system is not intended for use in cardiac procedures. The SynchroWave antennas may be used in open surgical procedures and in laparoscopic and percutaneous ablation procedures, using image guidance, including partial or complete ablation of non-resectable liver tumors. An optional TempSure temperature sensor may be used to monitor tissue temperatures.

TECHNOLOGICAL COMPARISON

The MTX device with an expanded indication for use in laparoscopic procedures and for ablation of non-resected liver tumors has the same intended use and employs the same technology as the currently marketed MTX-180 devices. The expanded indication for use in laparoscopic procedures and for ablation of non-resected liver tumors are cleared indications for use of the Valleylab Microwave Ablation System.

PERFORMANCE TESTING

The design of the new MTX device is identical to that of the already cleared MTX-180 predicate device. However, additional testing was conducted to show compliance to FDA's new requirements established as part of Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery - Draft Guidance for Industry and Food and Drug Administration Staff, issued on March 24, 2014. The MTX has been shown to meet the applicable portions of the following standards and guidance documents and in-house requirements.

- IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) IEC 60601-2-6:2012, EN 60601-1:2006, Medical Electrical Equipment – Part 1: General Requirements For Basic Safety & Essential Performance,

- IEC 60601-2-2 (ed. 5) 2009, 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
- IEC 60601-2-6:2012, (ed. 2.0) Medical electrical equipment – Part 2-6: Particular requirements for the basic safety of microwave therapy equipment
- IEC 60601-1-2 Medical Device (ed.3) (2007), EN 55011 Emissions Class A (2007), EN 61000-3-2 AC Current Harmonic Emissions (2006)A1(2009)A2(2009), EN 61000-3-3 Voltage Fluctuations Emissions (2008) Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests. (Includes compliance to CISPR 11 ed. 5.0 (2009), Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radiofrequency Equipment.)
- ISO 594-1:1986, Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements.
- ISO 594-2:1998, Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings.
- IEC 60601-2-18 Ed. 3.0 b:2009, Clause 201.11.101.2(c) Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- Premarket Notification [510(k)] Submissions for Electrosurgical Devices for General Surgery - Draft Guidance for Industry and Food and Drug Administration Staff, issued on March 24, 2014

- Internal safety and performance requirements for:
  - Software control of delivered power
  - Alerts and Shut-offs
  - Temperature of applied parts
  - Cooling circuit function
  - Ablation zone sizes
  - Accuracy of temperature measurement by TempSure Temperature Sensors
  - Usability

The results of all testing performed demonstrates conformance with applicable, external standards or internal requirements and/ or equivalence with the predicate device.

BIOCOMPATIBILITY ASSESSMENT

Patient-contacting materials used in the new MTX and currently marketed MTX-180 systems are identical, as are the processes used in their manufacture. The MTX has been shown to meet the applicable portions of the following biological safety standards, as modified by FDA Memo G95-1.

- ISO 10993-1: 2009, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process.

- ISO 10993-7: 2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals

STERILIZATION METHOD

The new MTX and currently marketed MTX-180 systems are sterilized using identical validated 100% EO sterilization cycle parameters. The MTX Antenna Kits with Cooling Circuits and Temperature Sensor Kits are sterilized by 100% Ethylene Oxide (EO). The MTX has been shown to meet the applicable portions of the following standard.

- ANSI/AAMI/ISO 11135-1:2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.

ANIMAL AND CLINICAL TESTING

A retrospective clinical study provided data collected from the ablation of 51 lesions in 31 patients using the MTX System. The data demonstrated that the MTX System can be used to treat non-resectable liver tumors and confirmed the results of a porcine study in which the MTX was used to perform 18 ablations in liver and 22 ablations in lung. The results from this testing support a substantial equivalence decision.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.