DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 13, 2017

Medtronic Advanced Energy
Lydia Sakakeeny, Ph.D.
Principal Regulatory Affairs
Specialist
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Portsmouth, New Hampshire
03801

Re: K170610
Trade/Device Name: PlasmaBlade T
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: February 28, 2017
Received: March 1, 2017

Dear Dr. Sakakeeny:

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)*
K170610

Device Name
PlasmaBlade T

Indications for Use *(Describe)*

The PlasmaBlade T is a monopolar, single use, sterile, disposable device intended for use with the AEX Generator. The device delivers RF energy concurrent with saline for hemostatic sealing and coagulation of soft tissue and bone and RF energy for cutting and coagulation of soft tissue. It is intended for, but not limited to, General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal, Thoracic, and Open abdominal surgery procedures.

The PlasmaBlade T should not be used on small appendages or body parts, as in circumcision. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

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

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Date Summary Prepared: February 28, 2017

Device Trade Name: PlasmaBlade T

Common Name: Electrosurgical Instrument

Classification Name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

Product Code: GEI

Predicate Device: PlasmaBlade T and AEX Generator (K143175)
Aquamantys SBS 5.0 (K111732, K132974)
PlasmaBlade 3.0S (K093695)

Device Description: The proposed single-use disposable accessory device, the PlasmaBlade T monopolar handpiece, provides the hemostatic capabilities of the Aquamantys SBS 5.0 Handpiece (Cleared under K111732, K132974) and the cutting and coagulative capabilities of the PEAK PlasmaBlade 3.0S (Previously cleared under K093695).

The proposed PlasmaBlade T Handpiece device is a monopolar, single use, disposable device and is provided sterile. The devices are not intended for reuse or resterilization. The PlasmaBlade T handpiece consists of an enamel coated insulated blade electrode with an uncoated circular electrode, an insulated telescoping shaft, handle with three integrated controls, and a co-extruded cable assembly to provide both power and saline. The seven-pin electrical connector is designed to be plugged into the AEx Generator (Cleared under K143175).

The proposed PlasmaBlade T Handpiece is a disposable device, that when connected to the AEX Generator (K143175), uses monopolar RF energy for the resection and coagulation of soft tissue and bone. The proposed PlasmaBlade T Handpiece device provides similar resection and coagulative effect to the predicate device, the PlasmaBlade 3.0S Monopolar Handpiece (Cleared under K093695).

In addition to the monopolar cutting and coagulation capabilities the proposed PlasmaBlade T Handpiece device also uses monopolar RF energy concurrent with saline delivery to provide a broader coagulative effect; similar to the predicate Aquamantys SBS 5.0 Handpiece (Cleared under K111732, K132974), this result is trademarked as Transcollation® Technology by Medtronic. The proposed PlasmaBlade T Handpiece

device also has a pump header tubing segment and saline bag spike tubing allowing the user to manually connect the device to saline source in the OR as well as the AEX Generator's peristaltic pump. This ensures the device is connected for saline delivery at the same time as the device is connected electrically to the proposed AEX Generator.

Indications for use:

The PlasmaBlade T is a monopolar, single use, sterile, disposable device intended for use with the AEX Generator (K143175). The device delivers RF energy concurrent with saline for hemostatic sealing and coagulation of soft tissue and bone and RF energy for cutting and coagulation of soft tissue. It is intended for, but not limited to, General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal, Thoracic, and Open abdominal surgery procedures.

The PlasmaBlade T should not be used on small appendages or body parts, as in circumcision. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Technological Characteristics:

The predicates and PlasmaBlade T are intended for RF based resection and coagulation of soft tissue, as well as RF based hemostatic sealing concurrent with saline delivery for hemostatic sealing and coagulation of soft tissue and bone during various surgical procedures. The proposed devices share the same operational characteristics as the predicate platforms, comprised of a radio-frequency generator which supplies RF power to disposable electrode devices for electrosurgical procedures.

The proposed single-use disposable accessory device, the PlasmaBlade T monopolar handpiece, provides the hemostatic capabilities of the Aquamantys SBS 5.0 Handpiece (Cleared under K111732, K132974) and the cutting and coagulative capabilities of the PEAK PlasmaBlade 3.0S (Previously cleared under K093695).

Summary of Non-Clinical Testing:

The design and performance of the modified PlasmaBlade T were verified and validated through bench testing. Medtronic product development processes and the finalized FDA Guidance Document, Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff issued on August 15, 2016, were utilized to determine applicable bench testing requirements.

Bench testing included the following:

- Sterilization
- Transit
- Shelf Life
- Biocompatibility
- Electrical Safety/EMC
- Mechanical Testing
- Activation Testing

In-vivo testing on an animal model was completed to confirm that the proposed device performed adequately to its predicates for its intended use. The testing met the criteria outlined in the FDA Guidance Document, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff" issued on August 15, 2016.The in-vivo testing determined the zone of thermal damage imparted on the tissue by the proposed devices was comparable to the predicates.

The bench and animal testing demonstrated that the performance and tissue effect of the proposed devices are substantially equivalent to that of the predicate devices and do not raise any concerns of device safety or efficacy.

Summary of Clinical Tests: Clinical testing was not required for this product.

Conclusion: The indications for use, technology and performance characteristics of the modified PlasmaBlade T are equivalent to the predicate devices' and therefore Medtronic Advanced Energy claims substantial equivalence to the predicate devices.