August 2, 2018

Medtronic Advanced Energy
Heather Valley
Principal Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

Re: K181257
Trade/Device Name: PlasmaBlade X 3.0S, PlasmaBlade X 4.0
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 9, 2018
Received: May 11, 2018

Dear Heather Valley:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181257

Device Name
PlasmaBlade X 4.0 and PlasmaBlade X 3.0S

Indications for Use *(Describe)*
The Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological procedures.

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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Medtronic

510(k) Summary K181257

Submitter:

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Portsmouth, NH 03801

Contact Person:

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Date Summary Prepared:

May 09, 2018

Device Trade Name:

PlasmaBlade X 4.0
PlasmaBlade X 3.0S

Common Name:

Electrosurgical Instrument

Classification Name:

Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

Product Code:

GEI

Predicate Devices:

PlasmaBlade 4.0 (K073057 Original Submission, K082786 Expanded Indications)
PlasmaBlade 3.0S (K093695)

Device Description:

PlasmaBlade X 4.0
The PlasmaBlade™ X 4.0 is a single-use- only device designed for use with qualified Generators as a System (Surgery System). The PlasmaBlade™ X has integrated hand switch control, or alternatively, may be controlled with a qualified Footswitch, supplied as an optional accessory to the Generator. The PlasmaBlade™ X 4.0 consists of a single bendable shaft and rotatable nose piece that can be adjusted by hand. The system components are designed to be used together and operated as a single unit.

PlasmaBlade X 3.0S
The PlasmaBlade™ X 3.0S is a single-use, monopolar RF device. It is designed to be used with the qualified Generators as part of the Surgery System. It can be operated with the integrated hand switch or a qualified Footswitch. The PlasmaBlade™ X 3.0S consists of a single bendable blade and telescoping shaft that can be configured

	in both standard and extended length. The finger grip also incorporates a suction lumen for the evacuation of smoke and fluids.
Indications for Use:	**Device Name:** PlasmaBlade X 4.0 **Indications:** The Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological procedures. **Device Name:** PlasmaBlade X 3.0S **Indications:** The Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological procedures.
Technological Characteristics:	The predicate PlasmaBlade devices and proposed PlasmaBlade X family of devices are intended for RF based cutting and coagulation. 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.
Summary of Non-Clinical Testing:	Design and material changes were verified through bench testing. Comparative performance testing was conducted in an in-vivo/ex-vivo animal model to determine thermal effect of the X series against the predicates. The thermal effect of the X series of products was found to be substantially equivalent to that of the predicate devices.
Summary of Clinical Tests: **Conclusion:**	Clinical Testing was not required for these products. The indications for use, technology and performance characteristics of the PlasmaBlade X devices are equivalent to the predicate devices, as such, Medtronic Advanced Energy claims substantial equivalence to the predicates.