DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 20, 2017

Medtronic Advanced Energy
Ms. Lydia Sakakeeny
Principal Regulatory Affairs Specialist
180 International Drive
Portsmouth, New Hampshire 03801

Re: K170296
Trade/Device Name: Corecath 2.7s
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 27, 2017
Received: January 31, 2017

Dear Ms. 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)*
K170296

Device Name

CoreCath 2.7S

Indications for Use *(Describe)*

The CoreCath 2.7S is a single use electrosurgical instrument designed to be used with flexible bronchoscopes and qualified electrosurgical units. It is indicated for cutting of soft tissue obstructions in upper airways and tracheobronchial tree, providing electrosurgical hemostasis, and evacuation of surgical smoke during such 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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510(k) Summary (K170296)

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Date Summary Prepared: January 27, 2017

Device Trade Name: CoreCath 2.7S (K170296)

Common Name: Electrosurgical Instrument

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

Product Code: GEI

Predicate Device: EC 2.7 Endoscopic Cutter (K120909)

Device Description: The CoreCath 2.7S is a disposable, single-use monopolar RF (radio-frequency) surgical device intended to be use for ablation and hemostasis of soft tissue obstructions in upper airways and tracheobronchial tree.

The CoreCath 2.7S is terminally sterilized via ETO. It is comprised of a cylindrically shaped, disposable monopolar cutting and coagulation electrode affixed to the distal end of a polymeric, flexible multi lumen shaft and cabling, intended for connection to the monopolar output port of the Medtronic Advanced Energy AEX Generator (K143175).

The CoreCath 2.7S is intended to be energized for use by the footswitch accessory supplied with the AEX Generator. It has an active length of approximately 750 mm and a maximum diameter crossing profile of 2.68 mm. It is sized such that may be delivered through the working channel of a flexible bronchoscope 2.8 mm diameter working channel and working length of 600 mm.

Indications for use: The CoreCath 2.7S is a single use electrosurgical instrument designed to be used with flexible bronchoscopes and qualified electrosurgical units. It is indicated for cutting of soft tissue obstructions in upper airways and tracheobronchial tree, providing electrosurgical hemostasis, and evacuation of surgical smoke during such procedures.

Technological Characteristics: The CoreCath 2.7S is similar to the predicate device in that they are single use, sterile, electrosurgical instruments used to cut and coagulate soft tissue obstructions in upper airways and tracheobronchial tree, while providing electrosurgical hemostasis. In addition, the subject device includes a suction feature enabling the suction of smoke during the

indicated procedures. This additional feature does not impact the safety or effectiveness of the device.

Summary of Non-Clinical Testing:

The design and performance of the modified CoreCath 2.7S were verified and validated through bench testing.

Bench testing included the following:

- Sterilization
- Transit
- Shelf Life
- Biocompatibility
- Electrical Safety
- EMC
- Endoscope Compatibility
- Mechanical Testing
- Activation Testing
- Suction Testing

Comparative performance testing was conducted in an in-vivo animal model. Ex-vivo tissue testing was also completed. Thermal effect of the CoreCath 2.7S in both the in-vivo and ex-vivo model was substantially equivalent to that of the predicate device.

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

Conclusion: The indications for use, technology and performance characteristics of the CoreCath 2.7S device are equivalent to the predicate device and therefore Medtronic Advanced Energy claims substantial equivalence to the predicate devices.