September 7, 2017

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

Re: K170381

Trade/Device Name: Aquamantys MIS FLEX and Aquamantys MIS FLEX Mini
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 18, 2017
Received: August 21, 2017

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. 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 (DICE) 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 (DICE) 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 -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
Indications for Use

Device Name
Aquamantys™ Minimally Invasive Sealer (MIS) FLEX
Aquamantys™ Minimally Invasive Sealer (MIS) FLEX Mini

Indications for Use (Describe)
The Aquamantys™ Minimally Invasive Sealer (MIS) FLEX and Aquamantys™ Minimally Invasive Sealer (MIS) Flex Mini are sterile, single-use bipolar electrosurgical devices intended to be used in conjunction with a qualified Pump Generator for delivery of Radio-frequency (RF) energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. They are intended for, but not limited to orthopaedic, neurosurgical, spine, endoscopic procedures, abdominal and thoracic surgery, and epidural vein sealing during surgery. These devices are 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

Submitter: Medtronic Advanced Energy
180 International Drive
Portsmouth, NH 03801

Contact Person: Heather Valley, RAC
Principal Regulatory Affairs Specialist
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Date Summary Prepared: September 5, 2017

Device Trade Name: Aquamantys™ Minimally Invasive Sealer (MIS) FLEX and Aquamantys™ Minimally Invasive Sealer (MIS) FLEX Mini

Common Name: Electrosurgical Instrument

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

Regulatory Class: Class II

Product Code: GEI

Predicate Device: Aquamantys SBS 5.0 (K132974)

Device Description: MIS FLEX and MIS FLEX Mini are single-use, disposable, bipolar devices. The MIS FLEX and MIS FLEX Mini employ radio-frequency (RF) energy and saline irrigation (termed Transcollation Technology™) for hemostatic sealing and coagulation. The devices are equipped with dual electrode tips while saline and electrical lines exit the opposite end of the handpiece from the electrodes. The handpiece is equipped with an on-off button that simultaneously activates both RF and saline flow. A saline fluid delivery line is provided with the device and includes a section of pump tubing and drip chamber or spike. The three-pin electrical connector is designed to be plugged into either of the FDA cleared AEX (K143175) or Aquamantys (K052859) Pump Generators.

The MIS FLEX devices feature a fully malleable shaft, altered saline delivery and dual ports for saline delivery (two for each electrode). The distal end of the device features small, rounded electrode geometry.

The MIS FLEX and MIS FLEX Mini differ by the length of the shaft. The MIS FLEX is designed for transsphenoidal and MIS Spine procedures while the MIS FLEX Mini is designed for craniotomies with application in posterial cervical and other spinal procedures.

Indications for Use: The Aquamantys™ Minimally Invasive Sealer (MIS) FLEX and Aquamantys™ Minimally Invasive Sealer (MIS) Flex Mini are sterile, single-use bipolar electrosurgical devices intended to be used in
conjunction with a qualified Pump Generator for delivery of Radio-frequency (RF) energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. They are intended for, but not limited to orthopaedic, neurosurgical, spine, endoscopic procedures, abdominal and thoracic surgery, and epidural vein sealing during surgery. These devices are not intended for contraceptive tubal coagulation (permanent female sterilization).

Technological Characteristics:
The MIS FLEX devices are similar to the predicate devices as they are sterile, single use, bipolar electrosurgical devices used to provide hemostatic sealing and coagulation of soft tissue and bone at the operative site.

The three major differences between the subject and predicate device are the malleable shaft, altered saline delivery and electrode size. These new features do not impact the safety or effectiveness of the device.

Summary of Non-Clinical Testing:
The design and performance of the MIS FLEX devices were verified and validated through bench testing. The following performance data were provided in support of the substantial equivalence determination:

- Biocompatibility
- Sterilization
- Shelf Life
- Electrical Safety
- Electromagnetic Compatibility
- Mechanical Testing
- Performance Testing

Biocompatibility Testing
The Biocompatibility evaluation for MIS FLEX was conducted in accordance with the following International Standard ISO-10993-1, “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process”, as recognized by FDA. The testing includes the following:

- InVitro Cytotoxicity
- Acute System Toxicity
- Irritation or Intracutaneous Reactivity
- Sensitization
- Pyrogenicity

The MIS FLEX devices are considered externally communicating devices (Tissue/Bone/Dentin) with limited exposure of less than 24 hours.
**Electrical Safety Testing**

Electrical safety and EMC testing were conducted on MIS FLEX devices and were found to be in compliance with associated IEC 60601-1 and IEC 60601-2-2 standards.

**Performance Testing**

Two studies were completed in support of the MIS FLEX 510(k). One study was limited to validating anatomical access (Cadaver Study). The second study was a comparative performance test, which was conducted in an in-vivo porcine model. Ex-vivo tissue testing was also completed.

The access study was conducted to ensure that the MIS FELX will be able to access key anatomy and meet customer needs for neurosurgical and spine procedures. The devices met the requirements for access.

The comparative performance testing assessed the thermal effect of the MIS FLEX devices in both the in-vivo and ex-vivo models against the predicate in accordance with the "Premarket Notification (510(k) Submissions for Electrosurgical Devices for General Surgery Guidance for Industry and Food and Drug Administration Staff". The subject devices were substantially equivalent.

Testing of the MIS FLEX and MIS FLEX Mini were conducted in accordance with the following FDA recognized standards:

<table>
<thead>
<tr>
<th>Recognition Number</th>
<th>Standard</th>
<th>Title of Standard</th>
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<tbody>
<tr>
<td>9-64</td>
<td>IEC 60601-2-2Ed 5.0</td>
<td>Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgery Equipment And High Frequency Surgical Accessories</td>
</tr>
<tr>
<td>14-479</td>
<td>11135:2014</td>
<td>Sterilization Of Health Care Products - Ethylene Oxide - Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices.</td>
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</table>
Summary of Clinical Tests: Clinical testing was not required for this product.

Conclusion: The indications for use, technology and performance characteristics of the MIS FLEX and MIS FLEX Mini are equivalent to that of the predicate device and therefore Medtronic Advanced Energy claims substantial equivalence to the predicate device.