K123201

510(k) Summary

JAN 10 2013

Submitter:	Medtronic Advanced Energy 180 International Drive Portsmouth, NH 03801 USA
Contact Person:	Tara N. Turney, RAC Senior Regulatory Affairs Specialist Phone: 603-742-5445 Fax: 603-742-1488 Email: tara.n.turney@medtronic.com
Date Prepared:	October 11th, 2012
Trade Name:	Aquamantys Endo DBS 8.7 Dissecting Bipolar Sealer
Common Name:	Electrosurgical accessory
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories
Predicate Device:	Aquamantys Double Cone Bipolar Sealer (K101057) Monopolar Floating Ball (K010662)
Device Description:	The Aquamantys Endo DBS 8.7 device is a handheld "wand-like" disposable that, when connected to the Aquamantys Pump Generator, uses bipolar radio-frequency energy concurrent with saline for hemostatic sealing and coagulation. The device is equipped with dual electrodes at the distal tip. Saline and electrical lines enter from the opposite end (proximal end) of the device's hand piece from the distal electrodes. The device's hand piece is equipped with a blue button that activates bipolar RF energy concurrent with saline flow for blunt dissection and for hemostatic sealing and coagulation. The long, stainless steel shaft allows for the device to be used in laparoscopic, endoscopic and thoracoscopic procedures. A saline fluid delivery line is provided with the device, which includes a drip chamber/spike for insertion into saline bags. The proposed device connects to the Aquamantys Pump Generator using a three-pronged connector.

Statement of Intended Use:

The Aquamantys Endo DBS 8.7 Dissecting Bipolar Sealer is a single use, sterile, bipolar device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of radio-frequency (RF) energy and saline for blunt dissection and for haemostatic sealing and coagulation of soft tissue at the operative site. It is intended for, but not limited to, abdominal, and thoracic surgery, endoscopic, laparoscopic, and thoracoscopic procedures.

The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Summary of Technological Characteristics:

The Aquamantys Endo DBS 8.7 Dissecting Bipolar Sealer applies the same fundamental scientific technology as the existing Medtronic Advanced Energy Aquamantys devices. The device's hand piece is equipped with a blue activation buttons that activates bipolar RF energy concurrent with saline flow for blunt dissection and for hemostatic sealing and coagulation. The device is designed to connect to the Aquamantys Pump Generator, providing connection to both RF power and the peristaltic pump for saline flow. The main differences between the proposed and predicate devices are as follows:

- Tip Configuration
  - Clamshell tip housing with saline exit
  - Smaller electrodes
- Shaft Material
  - Stainless steel

Summary of Non-clinical Data:

The Aquamantys Endo DBS 8.7 Dissecting Bipolar Sealer has undergone bench performance testing to verify and validate the performance features and specifications. The testing included:

- visual,
- static cable pulls,
- dynamic cable pulls,
- static saline tube pulls,
- air leak and flow,
- hipot testing,
- saline flow testing,
- shaft deflection/pull,
- electrode pull,
- continuity
- biocompatibility assessment,

- animal tissue testing, and
- electrical safety

Summary of Clinical Data: Clinical testing was not required to establish substantial equivalence between the proposed and predicate devices.

Conclusion from Data: Medtronic Advanced Energy has demonstrated that the Aquamantys Endo DBS 8.7 Dissecting Bipolar Sealer is substantially equivalent to the predicate devices based upon indications for use, design, test results and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Advanced Energy, LLC
% Ms. Janet Kwiatkowski
Regulatory Affairs Manager
180 International Drive
Portsmouth, New Hampshire 03801

January 10, 2013

Re: K123201
Trade/Device Name: Aquamantys Endo DBS 8.7
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 11, 2012
Received: October 12, 2012

Dear Ms. Kwiatkowski:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123201

Device Name: Aquamantys Endo DBS 8.7

Indications for Use: The Aquamantys Endo DBS 8.7 Dissecting Bipolar Sealer is a single use, sterile, bipolar device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of radio-frequency (RF) energy and saline for blunt dissection and for haemostatic sealing and coagulation of soft tissue at the operative site. It is intended for, but not limited to, abdominal, and thoracic surgery, endoscopic, laparoscopic, and thoracoscopic procedures.

The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
2013.01.08 14:40:12 -05'00'

(Division Sign-Off)

Division of Surgical Devices

510(k) Number ___K123201_____