DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 8, 2016

Medtronic Advanced Energy
Lydia Sakakeeny, Ph.D.
Principal Regulatory Affairs Specialist
180 International Drive
Portsmouth, NH 03801

Re: K152703
Trade/Device Name: PlasmaBlade TnA Tonsil and Adenoid Dissection Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 7, 2016
Received: June 8, 2016

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 yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K152703

Device Name:
PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device

Indications for Use:
The PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device is indicated for cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including adenoidectomy and tonsillectomy (Pharyngeal, Tubal, Palatine).

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 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)

Medtronic

510(k) Summary

Submitter:	Medtronic Advanced Energy 180 International Drive Portsmouth, NH 03801
Contact Person:	Lydia Sakakeeny, PhD Principal Regulatory Affairs Specialist Phone: (603) 294-5482 Fax: (603) 742-1488 E-mail: lydia.sakakeeny@medtronic.com
Date Summary Prepared:	September 10, 2015
Device Trade Name:	PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device
Common Name:	Electrosurgical Instrument
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Product Code:	GEI
Predicate Device:	K083415 PEAK PlasmaBlade TnA Tonsil and Adenoid Tissue Dissection Device K014290 (Original) Arthrocare ENT Plasma Wands
Device Description:	The PEAK PlasmaBlade® TnA is a single-use, disposable, electrosurgical instrument consisting of two PlasmaBlade tips (Tonsil tip and Adenoid tip) designed to be attached to the PlasmaBlade ENT handpiece (cleared as the PEAK PlasmaBlade TnA handpiece via K083415). The device also includes a wire cleaning brush designed to remove eschar build up and maintain a clear channel for suction. The Adenoid Tip consists of a wire electrode housed in a plastic tip with a bendable suction lumen that allows for the evacuation of tissue, fluids, and smoke. It connects to the suction shaft of the handpiece. These device is used with PULSAR I (K073057), PULSAR II (K102029) and AEX (K143175) Electrosurgical Generators. It provides radio-frequency energy for cutting and coagulation of soft tissue. The PEAK PlasmaBlade ENT handpiece has integrated buttons for Cut and Coag, which may be used to operate the device, or it may be activated with an optional footswitch supplied with the Generators.
Intended Use:	The PEAK PlasmaBlade TnA device is only indicated for cutting and coagulation of soft tissue during otolaryngology (ENT) surgery including adenoidectomy and tonsillectomy (Pharyngeal, Tubal, Palatine).
Technological Characteristics:	The PEAK PlasmaBlade TnA, Adenoid Tip is similar to the predicate devices in that they are single use, sterile, electrosurgical instruments used to cut and coagulate soft tissue utilizing RF powered distal ends. All enable the suction of fluid and smoke from the surgical site.

Technological differences between the modified adenoid tip and its predicates exist however they do not adversely impact the safety or efficacy of the devices.

For example, the modified adenoid tip and the original PEAK PlasmaBlade Adenoid tip are monopolar electrosurgical instruments with same operating principle, the modified tip utilizes a wire electrode while the predicate utilizes a blade electrode.

Similarly, while ENT Plasma Wands provide bipolar RF energy coupled with saline to the operatvie site and the PEAK PlasmaBlade adenoid tip delivers monopolar RF energy to the operative site, in vivo pre-clinical testing has confirmed that the thermal damage imparted by the two technologies are equivalent and does not raise concerns over safety or efficacy.

Summary of Non-Clinical Testing:

The design and performance of the modified Adenoid Tip were verified and validated through bench testing.

Comparative performance testing was conducted in an in-vivo animal model. Thermal effect of the PEAK PlasmaBlade Adenoid Tip in the in-vivo model was substantially equivalent to that of the predicate device.

All bench and pre-clinical testing that testing confirmed that the different technological characteristics of the subject device and the respective predicates do not raise any new issues of safety or effectiveness.

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

Conclusion: The indications for use, technology and performance characteristics of the modified PEAK PlasmaBlade TnA (specifically the Adenoid Tip) are equivalent to the predicate devices' and therefore Medtronic Advanced Energy claims substantial equivalence to the predicate devices.