DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 11, 2017

Spiration, Inc.
Cheryl Frederick
Executive Director, Regulatory Affairs & Quality Assurance
6675 185th Avenue NE
Redmond, Washington 98052

Re: K170990
Trade/Device Name: Active Needle Endoscopic Treatment (ANET) Electrosurgical Applicator
Regulation Number: 21 CFR 882.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, JOS
Dated: March 31, 2017
Received: April 3, 2017

Dear Ms. Frederick:

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)*
K170990

Device Name
Active Needle Endoscopic Treatment (ANET) Electrosurgical Applicator

Indications for Use *(Describe)*
The Spiration ANET Electrosurgical Applicator is indicated for coagulation and ablation of soft tissue when used in conjunction with a compatible radiofrequency generator.

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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K170990 - 510(k) Summary

Submitter Information

Date of 510(k) Summary Preparation: March 31, 2017

Name and Address of Manufacturer:

Spiration, Inc.
6675 185th Avenue NE
Redmond, WA 98052

Contact Person:

Cheryl Frederick
Executive Director, RA/QA
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Subject Device

Device Trade Name: **ANET Electrosurgical Applicator**
Common Name: RF Electrosurgical Electrode

Classification Regulation: Electrosurgical Cutting and Coagulation Device and Accessories
21 CFR 874.4400
Product Code: GEI, JOS
Review Panel: 79-General Surgery

Predicate Device

Trade Name: **Habib EUS RFA 6700**
510(k) Number: K150029, K161305
Manufacturer: EMcision LTD

Device Description

The Active Needle Endoscopic Treatment (ANET) Applicator (Model # ANET-00) is a disposable bipolar electrosurgical applicator intended for the coagulation and necrosis of soft tissue. Each Applicator consists of a needle (proximal electrode) with a coil (distal electrode). The needle and coil serve as the bipolar electrodes, so there is no need for an external ground pad.

The ANET Applicator is compatible with the cleared Olympus ESG-100 Electrosurgical Generator (K072307) and endoscopes with a working inner diameter of 2.2mm or greater, such as those cleared in K093395 and K100584. Other radiofrequency generators will be added as compatibility is established.

To perform ablation, the flexible catheter portion is first inserted into a compatible ultrasound endoscope working channel, then pushed forward until fully inserted. The handle is then affixed to the channel port of the endoscope via a mechanism locking onto the single use adapter biopsy

valve. The handle facilitates advancement of the needle/proximal electrode during puncture of the targeted ablation site. Once the proximal electrode is positioned, a separate handle control facilitates advancement of the distal electrode. Saline and power connections at the handle of the device deliver fluid (1-3cc/min) and energy respectively to the distal portion of the device. The needle size of the device is 19 gauge (19G). During operation, radiofrequency (RF) current is passed between the distal electrode and the proximal electrode to thermally coagulate the tissue.

The ANET device is provided sterile and is intended for single patient use. The device should only be used within a healthcare setting by physicians knowledgeable and experienced in RF ablation.

Device Materials (Patient Contacting)

The ANET Applicator is manufactured with materials commonly used in medical device applications. The patient contacting materials are included in **Table 5-1** below:

Table 5-1 ANET Patient Contacting Materials

Patient Contacting Materials
Acrylonitrile Butadiene Styrene (ABS)
304 Stainless Steel, 17-7PH Stainless Steel
Polyether/Polyamide
ABS, Polycarbonate, 304 Stainless Steel
Polyvinyl Chloride (PVC) Non-DEHP
Nitinol, Gold
Polyethylene Terephthalate (PET)
Silicone
Cyanoacrylate
Polytetrafluoroethylene (PTFE)
Polypropylene

Biocompatibility testing has been conducted on the ANET device to confirm that it meets the biocompatibility requirements per EN ISO 10993-1:2009 as an external communicating device with a limited blood path indirect exposure (<24 hours).

Ancillary Supplies

- ***Electrosurgical generator*** - The ANET Applicator is compatible with the Olympus ESG-100 Electrosurgical Generator (K073207). Additional Olympus generators will be added as compatibility is established.

- ***Ultrasound endoscope*** – The ANET Applicator is compatible with ultrasound endoscopes with a minimum inner working channel of 2.2mm or greater, such as those cleared in K093395 and K100584.
- ***Olympus biopsy valve*** – Model # MAJ-210 or MD-495

How Provided

The ANET Applicator is provided sterile and is disposable, intended for single patient use.

Proposed Indication for Use

The Spiration ANET Electrosurgical Applicator is indicated for coagulation and ablation of soft tissue when used in conjunction with a compatible radiofrequency generator.

Comparison to Predicate

Spiration has chosen the EMcision **Habib EUS RFA 6700** (K150029 & K161305) as the predicate for comparison to the proposed ANET Applicator. The predicate device, the Habib EUS RFA 6700 was initially cleared in K150029. The minor modifications to the device in K161305 were determined by the agency to not raise new issues of safety and effectiveness.

The Habib EUS RFA 6700 device described in both cleared 510(k) submissions have the same intended use, function and fundamental technology as the ANET Applicator.

A comparison table, **Table 5-2**, is included below, which illustrates the equivalence of the subject ANET device to the Habib EUS RFA 6700 device.

Table 5-2: Comparison of Key Characteristics of Proposed Device to Predicate Device

Device Name→ **Device Characteristics** ↓	**ANET Electrosurgical Applicator** **(Proposed Device)**	**Habib EUS RFA 6700** **(K150029)** **(K161305)**	**Differences**
Classification	II	II	Same
Code of Federal Regulations	878.4400	878.4400	Same
Prescription	Yes	Yes	Same
Indication for Use	The Spiration ANET Electrosurgical Applicator is *indicated for coagulation and ablation of soft tissue when used in conjunction with a compatible*	The Habib EUS RFA 6700 is *indicated for coagulation and ablation of soft tissue when used in conjunction with a compatible radiofrequency*	Same

	radiofrequency generator.	*generator***.**	
Anatomical Site of Use	Soft Tissue	Soft Tissue	
Compatible Electrosurgical Unit	Currently compatible with ESG-100 radiofrequency generator (K073207) as identified in IFU	Various compatible generators (identified in IFU)	Same – compatible with generators identified in labeling
Access Methods	Echoendoscope, laparoscope	Echoendoscope, laparoscope, trocar	Same
Principal of Operation	Operator controlled; RF delivered from compatible RF generator	Operator controlled; RF delivered from compatible RF generator	Same
Mechanism of Action	Cellular necrosis through thermal coagulation	Cellular necrosis through thermal coagulation	Same
Operating Mode	Bipolar - no grounding pad required*	Monopolar – requires a patient grounding pad, neutral electrode	ANET is bipolar, Habib is monopolar (grounding pad is required)
Minimum Scope Inner Channel	2.2 mm	2.4 mm	Similar – Difference 0.2 mm
19 Gauge Needle	Integrated into Device	Optional FNA Needle	Similar
Target Lesion Size (diameter)	10 - 30 mm	8 X 20 mm (between 5-10W)	Similar
Rated Frequency	Up to 650 kHz	Up to 460 kHz	Similar
Working Outer Diameter	2.0 mm	0.3 mm	ANET larger diameter

Working Length	69 cm	220 cm	Habib longer
Material Electrode Tip	Stainless Steel Needle with Nitinol Electrode	Stainless Steel	Similar
Insulation/Coating	PET between electrodes PEBAX over Stainless Steel Needle	Polyimide over Stainless Steel	Similar
Sterilization	Ethylene Oxide, Single Use	Ethylene Oxide, Single Use	Same
Shelf Life	6 months	3 years	ANET - Real time 1 year shelf life in progress

**The proposed ANET Electrosurgical Applicator is operated in bipolar rather than monopolar mode as compared to the predicate.*

The intended use of the subject device is virtually identical to that of the predicate device. In addition, the fundamental scientific technology, principle of operation and mechanism of action are similar enough to be considered substantially equivalent. Bench testing per the FDA Guidance Document, *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery*, indicates equivalence in performance.

Both devices use electrical energy to generate high-frequency (RF) energy as a means to coagulate tissue. In addition, both devices consist of an electrode for coagulation, user interface (handpiece) and connector/cable to the generator. And both devices are provided sterile, intended for single use only.

Although the predicate device is monopolar and the proposed device bipolar, we believe that RF experience supports that bipolar RF ablation is more controllable. As such, it is considered as safe if not safer than monopolar RF ablation, which also requires external grounding pads.

The Habib EUS RFA is designed to be used with a compatible, already cleared radiofrequency generator, same as the ANET Electrosurgical Applicator.

Performance Data

Performance testing has been completed to demonstrate substantial equivalence of the subject device to the predicate device. The ANET Applicator was subjected to the following verification and validation tests, as applicable:

Biocompatibility

Biocompatibility verification was performed for patient-contacting components of the ANET Applicator in accordance with ISO 10993-1 requirements, as well as the Guidance Document

Use of International Standard *ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process*," June 2016.

Sterilization/Shelf-Life

ANET was validated to achieve a sterility assurance level of 10^{-6} and adopted into a validated EO sterilization cycle. Packaging validation was performed to ensure that the devices maintain package integrity and sterility.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing was completed for the applicable components of the ANET Applicator. The results demonstrated compliance of the ANET Applicator to all applicable standard requirements.

Performance Testing

Mechanical and Functional Testing

Mechanical and Functional testing was completed to confirm that the performance of the ANET device conforms to the pre-determined mechanical, functional and packaging specifications at baseline and 6 months accelerated aging. Devices tested at baseline were post-sterilization (T=0), and devices tested at 6–months (T= 0.5) included devices that had been subjected to both sterilization and accelerated aging.

Comparative Bench-Top Validation Testing to Predicate

Direct comparative bench top validation testing was completed to demonstrate the substantially equivalent ablation performance of the subject device and the predicate in various tissue types. The results demonstrated that the lesion dimensions achieved by the ANET Applicator are equivalent to those obtained with the predicate device under the same test conditions and specified power levels.

Compliance with Standards

Applicable Standards	
Version	**Title**
EN ISO 14971, 2012	Medical Devices - Application of Risk Management to Medical Devices
EN ISO 10993-1, 2009	Biological Evaluation of Medical Devices - Evaluation and testing within a risk management process
EN ISO 10993-4:2009	Biological Evaluation of Medical Devices - Selection of tests for interactions with blood
EN ISO 10993-5, 2009	Biological Evaluation of Medical Devices- Tests for *in vitro* cytotoxicity
ISO 10993-10: 2013	Biological Evaluation of Medical Devices: Tests for irritation and skin sensitization
EN ISO 10993-11: 2009	Biological Evaluation of Medical Devices: Tests for systemic toxicity
EN ISO 10993-7, 2008	Biological evaluation of medical devices. Ethylene oxide sterilization residuals

EN ISO 11135-1, 2014	Sterilization of health care products. Ethylene oxide. Requirements for development, validation and routine control of a sterilization process for medical devices
EN 556-1: 2001	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
AAMI TIR28:2009	Product adoption and process equivalency for ethylene oxide sterilization
EN ISO 11607-1, 2009	Packaging for terminally sterilized medical devices. Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2, 2006	Packaging for terminally sterilized medical devices. Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2006/AC:2009	Sterilization of medical devices. Microbiological methods. Determination of a population of microorganisms on products
ISTA 3A, 2008	General Simulation Performance Test Procedure, Packaged Products for Parcel Delivery System Shipments 70 kg (150 lb) or Less
IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 2007	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-2-2:2009 Medical Electrical Equipment – Part 2-2	Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories
IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2	General Requirements for the Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
IEC 60601-2-18:2009 Medical Electrical Equipment – Part 2-18	Particular Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment

Conclusion (Statement of Equivalence)

The ANET device successfully passed all performance testing. Spiration believes that the data and information presented within this 510(k) Premarket Notification (including bench testing) support a determination of substantial equivalence to the predicate device, and market clearance of the ANET Electrosurgical Applicator.