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

April 7, 2017

Spectranetics, Inc.
Rebecca Spelich
Regulatory Affairs Specialist
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K170059
Trade/Device Name: Spectranetics Turbo-Elite Laser Atherectomy Catheters
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: March 10, 2017
Received: March 13, 2017

Dear Ms. Spelich:

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.

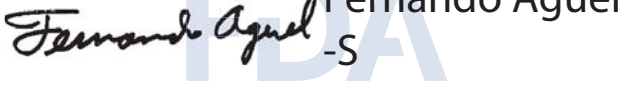
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K170059

Device Name
Spectranetics Turbo Elite Laser Atherectomy Catheter

Indications for Use *(Describe)*
The Turbo-Elite devices are indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions.

The 0.014" and 0.018" Over-the-Wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92

Updated on 6 April 2017

510(k) Submitter / Holder: Spectranetics
9965 Federal Drive
Colorado Springs, CO 80921.3617

Establishment Registration No: 3007284006

Contact: Ms. Rebecca Spelich
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Subject Device

Device Trade Name:	Spectranetics Turbo-Elite Laser Atherectomy Catheters
Device Common Name:	Laser Atherectomy Catheters
Device Class:	II
Classification Regulation:	21 CFR 870.4875, Intraluminal Artery Stripper
Regulation Description:	Cardiovascular
Product Code:	MCW
510(k) Type:	Traditional
Model Numbers:	410-152, 414-151, 417-152, 420-006, 423-001, 425-011

Predicate Device

The Turbo Elite Laser Catheters are being compared to the following legally marketed predicate device:

510(k) Number:	K140775
Manufacturer:	The Spectranetics Corporation
Trade Name:	Spectranetics Turbo-Elite® System
Device Common Name:	Percutaneous Laser Ablation Catheter

Indications for Use

The devices are currently cleared under K140775 with the following IFUs:

Turbo Elite: *The Turbo Elite devices are indicated for use in the treatment of infrainguinal stenosis and occlusions. When used in conjunction with the Turbo Booster and/or as an accessory to the Turbo Tandem System, the devices are indicated for atherectomy of infrainguinal arteries.*

The 0.014" and 0.018" Over-the-wire (OTW) Turbo Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

This 510(k) submission requested expansion of the IFU statements to:

Turbo Elite: *The Turbo-Elite devices are indicated for use in the treatment, including atherectomy, of infrainguinal stenoses and occlusions.*

The 0.014" and 0.018" Over-the-wire (OTW) Turbo-Elite laser catheters are also indicated for use as an accessory to the use of the Turbo-Tandem System in the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, when used in conjunction with Percutaneous Transluminal Angioplasty (PTA).

Device Description

Spectranetics Turbo-Elite Laser Ablation Catheters are percutaneous intravascular devices constructed of multiple optical fibers arranged around a guidewire lumen for Over-the-Wire (OTW) configurations, and bundled together for Rapid-Exchange (Rx) versions. Turbo Elite Laser Ablation Catheters are available in an Over the Wire (OTW) configuration and a Rapid Exchange (RX) configuration. The Turbo-Elite laser catheters in the OTW configuration are available in six different catheter tip sizes (0.9mm, 1.4mm, 1.7mm, 2.0mm, 2.3mm, and 2.5mm) and three different guide-wire compatibilities (0.014", 0.018", and 0.035"). New indication clearance is only being requested for the OTW configurations of Turbo-Elite catheters compatible with 0.014" and 0.018" guidewires.

The multifiber laser catheters transmit ultraviolet energy from the Spectranetics CVX-300® Excimer Laser System to an obstruction in the patient's artery. The ultraviolet energy is delivered to the tip of the laser catheter to photoablate fibrous, calcific, and atheromatous lesions, thus recanalizing diseased vessels. Photoablation is the process by which energy photons cause molecular bond disruption at the cellular level without thermal damage to surrounding tissue.

Technological Characteristics

There have been no changes to the design or function of the predicate devices. The only change being proposed is to the indication of use. The safety and effectiveness of the existing technological characteristics are being supported by clinical evidence.

Performance Data

The following testing was conducted to validate and verify that the subject device met all specifications and was substantially equivalent to the predicate device.

Design Verification and Validation Testing (submitted in support of prior 510(k)s)

The Spectranetics Corporation
9965 Federal Drive, Colorado Springs, CO 80921
Tel: 719-447-2000 • Fax: 719-447-2022

- Solarization
- Tissue ablation efficiency
- Physical testing
- Trackability
- Torquability
- Tensile
- Laser Lifetime
- Packaging stability

Bench testing submitted in support of IDE G140141 and this 510(k)

- Stent Fatigue testing (post lasing and visual inspection)
- Stent Axial, Bending, Torsion, and Fatigue Study (post – lasing and visual inspection)
- Stent corrosion testing (post lasing, inspection and fatigue testing)

Sterilization

- There have been no changes to the sterilization process for either the Spectranetics Turbo-Elite; therefore, the sterilization validation previously submitted under the existing 510(k) files is unchanged.

Biocompatibility:

- There have been no changes to the materials of construction, or manufacturing process for either the Spectranetics Turbo-Elite catheters, therefore the biocompatibility testing previously submitted under the existing 510(k) files is unchanged.

Clinical Data:

- The **A**therectomy **B**y **L**aser **A**blation with **T**urbo-**E**lite (ABLATE) clinical study was performed to demonstrate the safety and effectiveness of the Turbo-Elite in the treatment of patients with infrainguinal stenosis. The primary safety endpoint is percent freedom from major adverse events (MAE) through day 30 follow-up, which included all-cause death, major amputation in the target limb, or target lesion revascularizations (TLR). The primary effectiveness endpoint was a mean reduction in percent stenosis at the time of the procedure by Angiographic Core Lab assessment. Both primary safety and effectiveness hypotheses were met. Additional analyses were conducted to prove lesions had ≤50% residual stenosis post Turbo-Elite treatment and long-term freedom from TLR through 180-days. Both of these analyses were successful, with an average reduction of 42%.
- Procedural safety and effectiveness are clearly demonstrated for Turbo-Elite by the Primary Safety and Primary Effectiveness Endpoints, as well as the longer term data contained in this clinical study report. Based on the clinical data it is reasonable to conclude that Turbo-Elite performs atherectomy in accordance with the indicationss for use.

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