



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

November 12, 2015

Spectranetics, Inc.  
Ms. Priscila Tapia  
Regulatory Specialist  
9965 Federal Drive  
Colorado Springs, Colorado 80921

Re: K152181

Trade/Device Name: Turbo-Power Laser Atherectomy Catheter  
Regulation Number: 21 CFR 870.4875  
Regulation Name: Intraluminal Artery Stripper  
Regulatory Class: Class II  
Product Code: MCW  
Dated: October 13, 2015  
Received: October 14, 2015

Dear Ms. Tapia:

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

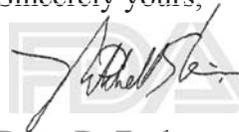
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152181

Device Name

Turbo-Power™ Laser Atherectomy Catheter

Indications for Use (Describe)

Turbo-Power™ Laser Atherectomy Catheter is indicated for laser atherectomy of de novo or restenotic lesions in native infrainguinal arteries and for the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, with adjunctive 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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### 510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92(c)  
 Prepared on 07 October 2015

<b>510(k) Submitter / Holder:</b>	Spectranetics 9965 Federal Drive Colorado Springs, CO 80921.3617 Establishment Registration No: 3007284006
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#### Subject Device

510(k) Number: K152181  
 Device Trade Name: Turbo-Power™ Laser Atherectomy Catheters  
 Device Common Name: Laser Atherectomy Catheter  
 Device Class: II  
 Classification Regulation: 21 CFR 870.4875, Intraluminal Artery Stripper

Regulation Description: Cardiovascular  
 Product Code: MCW  
 510(k) Type: Traditional  
 Model Numbers: 423-050

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#### Predicate Devices

The Turbo-Power Laser Atherectomy Catheter is being compared to the following legally marketed predicate devices:

Turbo-Tandem  
 510(k) Number: K140775  
 Manufacturer: The Spectranetics Corporation  
 Trade Name: Turbo-Tandem Laser Guide Catheter with Laser Atherectomy Catheter  
 Device Common Name: Percutaneous Laser Ablation Catheter

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

### **Intended and Indications for Use**

Turbo-Power™ Laser Atherectomy Catheter is indicated for laser atherectomy of de novo or restenotic lesions in native infrainguinal arteries and for the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, with adjunctive Percutaneous Transluminal Angioplasty (PTA).

### **Device Description**

The Turbo-Power System (Laser Atherectomy Catheter) is a laser atherectomy device designed for use with the CVX-300™ Excimer Laser System. The Turbo-Power Laser Atherectomy Catheter is a sterile, single use, prescription only device used for peripheral atherectomy.

Turbo-Power is used to directionally ablate infrainguinal concentric and eccentric lesions in vessels that are 3.5mm or greater in diameter. Turbo-Power Laser Atherectomy Catheter is comprised of 2 subassemblies:

1. Catheter Subassembly
2. Motor Drive Unit (MDU) Subassembly

The working length of the Turbo Power Laser Atherectomy Catheter is constructed of multiple optical fibers arranged eccentrically around a 0.018" (0.46 mm) guidewire-compatible lumen. The PTFE guidewire lumen tip is attached to a stainless steel torque wire which is connected to the MDU at the proximal end of the working length. The multifiber laser catheter transmits ultraviolet energy from the Spectranetics CVX-300 Excimer Laser System through the tip of the laser to an obstruction in the patient's artery. The outer surface of the laser catheter working length is hydrophilic-coated, and the distal tip of the catheter contains a radiopaque marker band for in situ visibility. The ultraviolet energy transmitted from the CVX-300 laser system is used to photoablate multiple morphology lesions which may be comprised of atheroma, fibrosis, calcium, and thrombus, 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.

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### **Technological Characteristics**

The debulking performance of the Turbo-Power was developed to be similar to the Turbo-Tandem system, while maintaining the ability to cross difficult lesion morphologies, un-crossable with a guidewire, similar to the Turbo-Elite laser catheter. The Turbo-Power allows physicians to use a single tool for the full atherectomy procedure. To improve ease of use, the Turbo-Power device has mechanized the rotation process of the Turbo-Tandem system. In addition, the distal tip design of the subject device has been simplified by removing the tapered biasing tip of the Turbo-Tandem from the Turbo-Power design.

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## Performance Data

The following testing was conducted to validate and verify that the subject device met all specifications:

- Simulated Use Testing
- Functional Testing
- Physical Testing
- Laser Testing
- Software Testing
- Sterility/Biocompatibility/Physiochemical Testing

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## Pre-clinical and Clinical Data:

In addition to the design verification and validation tests, a pre-clinical GLP study was conducted to compare the usability and procedural safety of the Turbo-Power and Turbo-Tandem laser catheters, and support this premarket notification.

New clinical data was not required to demonstrate substantial equivalence. The following clinical studies were leveraged to support the indications for use for Turbo-Power:

- Clinical Data:
  - The EXCITE trial evaluated the safety and efficacy of Excimer Laser Atherectomy (ELA) using the Spectranetics Turbo Elite Laser Ablation Catheter and the Spectranetics Turbo-Tandem Laser Guide Catheter with Laser Atherectomy Catheter with adjunctive percutaneous transluminal angioplasty (PTA) in comparison with PTA alone in the treatment of femoropopliteal bare nitinol in-stent restenosis in vessels  $\geq 5$ mm. This trial was a prospective randomized controlled trial performed respectively in a 2:1 randomization scheme. The primary safety hypothesis was that freedom from a major adverse event (MAE) through 30 days with ELA+PTA, which included all-cause death, major amputation in the target limb, or target lesion revascularization (TLR), would be non-inferior to PTA. The primary efficacy hypothesis was that freedom from TLR through 6 months with ELA+PTA would be superior to PTA. Both primary safety and efficacy hypothesis were met. There was no statistical difference in major amputation rates, mortality, serious adverse events, or adverse events between groups.
  - The PATENT study was a multicenter prospective registry involving 5 EU centers. The PATENT study was intended to evaluate the safety and performance of the Spectranetics peripheral atherectomy laser catheters (Turbo Elite) used in conjunction with Turbo-Booster catheters for the treatment of in-stent restenosis of nitinol stents implanted in the femoropopliteal arteries.
  - The CELLO (CLiRpath Excimer Laser System to Enlarge Lumen Openings) Study, was intended to study the safety and performance of the Turbo-Elite used in conjunction with Turbo-Booster catheters for the treatment of Peripheral Artery Disease (PAD). The primary effectiveness

endpoint was  $\geq 20$  percent reduction in percent diameter stenosis, on average, as assessed by an angiographic core lab. The secondary effectiveness endpoint was acute procedural success (visual assessment of final residual stenosis). The primary safety endpoint measured was the occurrence of major adverse events, defined as clinical perforation, major dissection requiring surgery, major amputation, cerebrovascular accidents (CVA), myocardial infarction, and death at the time of procedure, through six (6) months. The study demonstrated that the Turbo-Booster is safe for the treatment of patients with stenoses and occlusions crossable by a guidewire in the superficial femoral artery and popliteal artery as evident by no occurrence of major adverse events through the six-month follow-up.

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**Substantial Equivalence**

Based on the similarities in design between the subject and predicate devices currently in use, and the performance and pre-clinical data, the use of the Turbo-Power System for the proposed indication does not raise new questions related to safety and effectiveness compared with the predicates. Therefore Turbo-Power is substantially equivalent to Turbo-Tandem and Turbo-Elite.