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

January 5, 2017

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

Re: K162561
Trade/Device Name: Turbo-Power (2.0mm) Laser Atherectomy Catheter
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: September 12, 2016
Received: September 14, 2016

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,

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)*
K162561

Device Name
Turbo-Power (2.0mm) Laser Atherectomy Catheters

Indications for Use *(Describe)*
The Turbo-Power is indicated for laser atherectomy of de novo and restenotic lesions in native infrainguinal arteries and for the treatment of femoropopliteal artery in-stent restenosis (ISR) in bare nitinol stents, with adjunctive Pecutaneous 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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Spectranetics
Always Reaching Farther

510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92(c)
Prepared on September 12, 2016

510(k) Submitter / Holder:	The Spectranetics Corporation 9965 Federal Drive Colorado Springs, CO 80921.3617 Establishment Registration No: 3007284006
Contact:	Ms. Priscila Tapia Senior Regulatory Affairs Specialist Office: 719.447.2587 Mobile: 719.393.5354 Fax: 719.447.2070 Email: Priscila.Tapia@spnc.com

Subject Device

Device Trade Name:	Turbo-Power™ (2.0mm) 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:	420-050

Predicate Device

The Turbo-Power (2.0mm) Laser Atherectomy Catheter is being compared to the following legally marketed predicate device:

510(k) Number:	K152181
Manufacturer:	The Spectranetics Corporation
Trade Name:	Turbo-Power™ Laser Atherectomy Catheter
Device Common Name:	Laser Atherectomy Catheter
Model Number:	423-050

Intended and Indications for Use

Turbo-Power™ (2.0mm) 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 (2.0mm) Laser Atherectomy Catheter is a laser atherectomy device designed for use with the CVX-300™ Excimer Laser System. The Turbo-Power (2.0mm) Laser Atherectomy Catheter is a sterile, single use, prescription only device used for peripheral atherectomy.

The Turbo-Power (2.0mm) is used to ablate lesions with reference vessel diameters of ≥3.0mm. Turbo-Power (2.0mm) 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.

Technological Characteristics

The Turbo-Power (2.0mm) introduces a smaller size catheter that can reach smaller vessels (≥3.0mm), however, it does not affect the fundamental scientific technology used in the Turbo-Power family of devices. The mechanism of action, principle of operation, and intended use, remain unchanged from the predicate Turbo-Power (2.3mm).

Performance Data[1]

The following testing was conducted to validate and verify that the subject device met all acceptance criteria as required by the risk analysis that was performed:

Design Verification and Validation Testing

- Simulated Use Testing
- Functional Testing
- Physical Testing
- Laser Testing

Sterilization

- Product adoption equivalency per AAMI TIR:28-2009*

Biocompatibility

- Cytotoxicity
- Sensitization*
- Intracutaneous Reactivity*
- Acute Systemic Toxicity*
- Direct Hemolysis*
- Indirect Hemolysis*
- *In Vivo* Thrombogenicity-Ovine Model*
- Genotoxicity – Ames Test*
- Material Mediated Pyrogenicity*

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 (2.0mm) and the Turbo-Power (2.3) laser catheters, and support this premarket notification. New clinical data was not required to demonstrate substantial equivalence.

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 (2.0mm) Laser Atherectomy Catheter for the proposed indication does not raise new questions related to safety and effectiveness compared with the predicate. Therefore Turbo-Power (2.0mm) is substantially equivalent to Turbo-Power (2.3mm).

[1] All testing marked with an * is leveraged from the predicate Turbo-Power (2.3mm). Additional testing required is summarized within this submission.