December 8, 2022

Spectranetics Inc.
Taylor Olen
Regulatory Affairs Specialist
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K222837
Trade/Device Name: Turbo-Power™ (2.0mm and 2.3mm) Laser Atherectomy Catheters
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: November 15, 2022
Received: November 16, 2022

Dear Taylor Olen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory W. O'connell -S

Digitally signed by Gregory W. O'connell -S
Date: 2022.12.08 10:28:02 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222837

Device Name
Turbo-Power (2.0mm and 2.3mm) Laser Atherectomy Catheters

Indications for Use *(Describe)*
Turbo-Power 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92(c)
Prepared on November 22, 2022

510(k) Submitter / Holder:	The Spectranetics Corporation 9965 Federal Drive Colorado Springs, CO 80921.3617 Establishment Registration No: 3007284006
Contact:	Ms. Taylor Olen Regulatory Affairs Specialist Mobile: 719-437-4129 Fax: 719.447.2070 Email: taylor.olen@philips.com

Subject Device

Device Trade Name:	Turbo-Power™ (2.0mm, 2.3mm) 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) Number:	K222837
510(k) Type:	Special
Model Numbers:	420-050, 423-050

Predicate Device

The Turbo-Power™ (2.0mm and 2.3mm) Laser Atherectomy Catheters are being compared to the following legally marketed predicate device:

510(k) Number:	K180694 (cleared April 5,2018)
Manufacturer:	The Spectranetics Corporation
Trade Name:	Turbo-Power Laser Atherectomy Catheter
Device Common Name:	Laser Atherectomy Catheter
Model Number:	420-050, 423-050

Intended and Indications for Use

Turbo-Power 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, 2.3mm) Laser Atherectomy Catheter are laser atherectomy devices designed for use with the CVX-300™ Excimer Laser System and Philips Laser System. The Turbo-Power (2.0mm) and (2.3mm) Laser Atherectomy Catheters are sterile, single use, prescription only devices used for peripheral atherectomy.
The Turbo-Power (2.0mm) and (2.3mm) are used to ablate lesions with reference vessel diameters of ≥3.0mm. Turbo-Power (2.0mm) and (2.3mm) Laser Atherectomy Catheters are 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 or Philips 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 or Philips 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

This submission introduces a new Printed Circuit Board Assembly (PCBA) and firmware; however, it does not affect the fundamental scientific technology used in the Turbo-Power family of devices. The mechanism of action, and intended use, remain unchanged from the predicate Turbo- Power (2.0mm, 2.3mm). Functional testing was performed to confirm the devices with the new PCBA meet the relevant product requirements. Additionally, Software testing and Medical Electrical Safety Testing was performed on devices with the new PCBA.

Performance Data

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

Design Verification and Validation Testing

- Functional Testing
- Software Testing
- Medical Electrical Safety Testing

Sterilization

An assessment was conducted and concluded that additional sterilization testing was not required for the subject device to demonstrate substantial equivalence.

Pre-clinical and Clinical Data

No new pre-clinical or clinical data was 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 and 2.3mm) Laser Atherectomy Catheter for the new PCBA and firmware does not raise new questions related to safety and effectiveness compared with the predicate. Therefore Turbo-Power (2.0mm and 2.3mm) are substantially equivalent to Turbo-Power (2.3mm) and Turbo-Power (2.0mm) (K180694).