March 13, 2025

Spectranetics
Katie Adamski
Principal Regulatory Affairs Specialist
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K250385
Trade/Device Name: Turbo-Elite Laser Atherectomy Catheter
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: February 11, 2025
Received: February 11, 2025

Dear Katie Adamski:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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: 2025.03.13 09:14:40 -04'00'

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250385

Device Name

Turbo-Elite Laser Atherectomy Catheter

Indications for Use *(Describe)*

The Turbo-Elite devices are indicated for use in 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Turbo-Elite Laser Atherectomy Catheter
510(k) Summary

Submitter Information

Applicant: The Spectranetics Corporation
9965 Federal Drive
Colorado Springs, CO 80921
Phone: 719-447-2000
Contact: Katie Adamski, Principal Regulatory Affairs Specialist
Date: March 12, 2025

Subject Device

Device Trade Name: Turbo-Elite Laser Atherectomy Catheter
Common or Usual Name: Laser Atherectomy Catheter
Classification name of device: Intraluminal artery stripper
Product Code: MCW
Classification: Class II
Review Panel: Cardiovascular
Regulation Number: 21 CFR 870.4875

Predicate Device

Turbo-Elite Laser Atherectomy Catheter (K170059; cleared April 07, 2017)

Indications for use

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

Turbo-Elite laser atherectomy catheters are percutaneous intravascular devices constructed of multiple optical fibers in a concentric array around a guidewire lumen. The optical fibers are enclosed in an outer jacket and the working length of the device is coated with a hydrophilic coating. The distal tip of the catheter includes a Platinum Iridium outer Marker Band which is visible under fluoroscopy. The proximal end consists of a tail tube and a coupler which connects the device to the CVX-300 or PLS laser systems.

Turbo-Elite is designed and intended to be used exclusively with Spectranetics’ CVX-300 Excimer Laser System and Philips Laser System (PLS).

The catheters transmit ultraviolet energy from the laser system to the obstruction in the artery. The ultraviolet energy is delivered to the tip of the laser catheter to photoablate 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.

During a laser atherectomy, and under fluoroscopic guidance, a physician advances the introducer sheath to the target lesions. The Turbo-Elite catheters are then advanced to the proximal end of the lesion to be treated.

Substantial Equivalence

Indications for use

The indications for use for the subject device are the same as the predicate device.

Technological characteristics

The subject device has the same technological characteristics as the predicate device with no significant updates to device design, specification, or performance. The Instructions for Use (IFU) has been updated to add a new Warning with respect to advising for fluoroscopic monitoring during use, attention given for identifying possible marker band detachment, and steps that may be taken towards retrieval, as applicable. Other minor changes related to component suppliers and certain adhesives used were supported via applicable design verification and validation testing and related rationales. Therefore, these changes have no significant impact on Turbo-Elite's technology, engineering, specification, design, or materials and biocompatibility.

The subject device transmits ultraviolet energy from the laser system to the obstruction in the artery to photoablate lesions. The subject device has the same dimensional criteria as the predicate, including compatibility with introducer sheaths and guidewires, outer diameter, working length, and design. Materials of construction, including inner lumens, outer jackets, hydrophilic coating, and epoxy are all either the same or any differences have been supported between subject and predicate devices, and therefore are considered substantially equivalent.