1 510(k) Summary

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

Prepared on July 9, 2014

1.1 Subject Device

Device Trade Name	Spectranetics Turbo-Tandem System and Turbo Elite Laser Catheters
Classification Name	21 CFR 870.4875, Intraluminal Artery Stripper
Device Common Name	Turbo-Tandem: Percutaneous Laser Ablation Catheter Turbo Elite: Laser Atherectomy Catheters
Device Class	Class II
Classification Panel	Cardiovascular
Product Code	MCW
510(k) Type	Traditional
Model Numbers	Turbo-Tandem: 472-110 Turbo Elite: 410-152, 414-151, 417-152, 420-006, 423-001, 425-011
Sponsor	Spectranetics 9965 Federal Drive Colorado Springs, CO 80921
Establishment Registration No	3007284006
Primary Contact	Amanda M. Johnson Vice President of Regulatory and Medical Affairs Office: (719) 447-2452 Fax: (719) 447-2040 Email: **Amanda.Johnson@SPNC.com**
Secondary Contact	Ms. Christine Godleski Senior Regulatory Affairs Specialist Office: (719) 447-2432 Fax: (719) 447-2040 Email: **Christine.Godleski@SPNC.com**

1.2 Predicate Device

The Turbo-Tandem system is being compared to the following legally marketed predicate device:

510(k) Number	K094036, K091299
Manufacturer	The Spectranetics Corporation
Trade Name	Spectranetics Turbo-Tandem System
Device Common Name	Percutaneous Laser Ablation Catheter

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

510(k) Number	K060012, K052514, K052296
Manufacturer	The Spectranetics Corporation
Trade Name	Spectranetics Turbo Elite System
Device Common Name	Percutaneous Laser Ablation Catheter

1.3 Indications for Use

The devices are currently cleared with the following IFUs:

Turbo Elite: *For use in the treatment of infrainguinal stenoses and occlusions.*

Turbo-Tandem: *Indicated for atherectomy of infrainguinal arteries.*

Spectranetics is proposing the following new IFU statements based on clinical evidence:

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).*

Turbo-Tandem: *The 7 and 8 French Turbo-Tandem systems are indicated for atherectomy of infrainguinal arteries.*

The 7 French Turbo-Tandem System 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) only in bare nitinol stents, with adjunctive Percutaneous Transluminal Angioplasty (PTA). A > 2.0mm pilot channel must be present for treatment using the Turbo-Tandem.

1.4 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 Turbo-Tandem Laser Guide Catheter with Laser Atherectomy Catheter (Turbo-Tandem System) is a laser atherectomy catheter constrained within a guiding catheter to facilitate the offset (biased position) of the laser atherectomy catheter. The Turbo-Tandem System is designed to be used to directionally ablate infrainguinal concentric and eccentric lesions in vessels 5mm or greater at or above the knee. The Turbo Tandem Laser Guide Catheter with Laser Atherectomy Catheter is available in two sizes; a 7F and 8F with a 2.0mm equivalent laser catheter embedded in the system. New indication clearance is only being requested for the Turbo-Tandem 7F catheters.

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.

1.5 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, animal, and bench testing..

1.6 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.

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

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

1.6.2 Bench testing submitted in support of IDE G110039 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)

1.6.3 Sterilization

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

1.6.4 Biocompatibility:

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

1.6.5 Preclinical and Clinical Data:

- Pre-clinical Data: Pre-clinical testing was completed to demonstrate the safety of a 2.0mm Turbo Elite Laser Ablation Catheter for ablation treatment of in-stent restenosis via the porcine, stented peripheral artery injury model.
- Clinical Data: The EXCITE trial evaluated the safety and effectiveness 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 ≥5mm. 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. An additional analysis was also conducted to evaluate superiority for the safety endpoint. The primary effectiveness hypothesis was that freedom from TLR through 6 months with ELA+PTA would be superior to PTA. Both primary safety and effectiveness hypothesis were met. There was no statistical difference in major amputation rates, mortality, serious adverse events, or adverse events between groups.

1.7 Substantial Equivalence

The clinical data presented in this 510(k) was developed and collected through IDE G110039. Analysis of the data has shown superior safety and effectiveness results compared to PTA, which supports clearance of the device for the new indication. The currently marketed Turbo Elite and Turbo-Tandem product designs (materials, construction and specifications) are unchanged from their original design and performance specifications and are substantially equivalent.

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

July 23, 2014

Spectranetics Corporation
Ms. Amanda Johnson
Vice President of Regulatory & Medical Affairs
9965 Federal Drive
Colorado Springs, Colorado 80921-3617

Re: K140775
Trade/Device Name: Turbo-Tandem System, Turbo-Elite Atherectomy Catheters
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II
Product Code: MCW
Dated: June 20, 2014
Received: June 23, 2014

Dear Ms. Johnson,

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,

Nicole Gluck -S

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)*
K140775

Device Name
Turbo Elite Laser Catheter

Indications for Use *(Describe)*
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).

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.

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."