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 08, 2016

Spectranetics, Inc.
Stephanie Byrum
Regulatory Affairs Associate
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K161333
Trade/Device Name: TightRail Sub-C Rotating Dilator Sheath
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: May 11, 2016
Received: May 12, 2016

Dear Stephanie Byrum:

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,

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)*
K161333

Device Name
TightRail Sub-C Rotating Dilator Sheath

Indications for Use *(Describe)*
The TightRail Sub-C Rotating Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters, and foreign objects.

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.

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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 May 9, 2016.

510(k) Submitter / Holder: Spectranetics
9965 Federal Drive
Colorado Springs, CO 80921.3617
Establishment Registration No: 3007284006

Contact: Stephanie Byrum
Regulatory Affairs Associate
Office: 719.447.2671
Mobile: 719.482-4765
Fax: 719.447.2070
Email: Stephanie.byrum@spnc.com

Subject Device

Device Trade Name:	TightRail Sub-C Rotating Dilator Sheaths
Device Common Name:	Sheath
Device Class:	II
Classification Regulation:	21 CFR 870.1310
Regulation Description:	Vessel dilator for percutaneous catheterization
Product Code:	DRE
510(k) Type:	Traditional
Model Numbers:	560-009, 560-011, 560-013

Predicate Device

The TightRail Sub-C Rotating Dilator Sheaths were compared to the following legally marketed predicate devices:

510(k) Number:	K142546 (cleared 25 September 2014) and K150360 (cleared 4 March 2015)
Manufacturer:	Spectranetics
Trade Name:	TightRail and TightRail Mini Rotating Dilator Sheaths
Device Common Name:	Sheath

Device Description

The TightRail Sub-C Rotating Dilator Sheaths are mechanical, intra-operative devices. The devices consist of a proximal handle drive mechanism with a distal dilation catheter. The sheaths are packaged with an optional outer support sheath. The dilator sheath is advanced, withdrawn, and rotated about the lead, catheter or foreign object to be removed. Actuating the trigger on the proximal handle activates a rotary dilation mechanism sheathed at the distal terminus of the catheter. Rotation of the inner shaft is translated to axial actuation of the dilation mechanism via a cam path contained within the distal components. Actuation of the distal dilation mechanism causes dilation of tissue and fibrous attachments surrounding the object targeted for removal, thereby facilitating removal of said object. The diameter sizes range from 9 French (F) to 13 F. The nominal effective length of the TightRail Sub-C is 15.5 cm.

Intended and Indications for Use

The TightRail Sub-C Rotating Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters, and foreign objects.

The Spectranetics Corporation
9965 Federal Drive, Colorado Springs, CO 80921
Tel: 719-447-2000 • Fax: 719-447-2022

Technological Characteristics
The TightRail Sub-C Rotating Dilator Sheath features the same performance characteristics as the predicate devices (K142546 and K150360). There are no significant changes to the function of the device. Changes have been made to the inner and outer shaft. The predicate devices featured a tri-coil design while the subject device features a laser-cut hypotube.

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:

Design Verification and Validation Testing

- Dimensional Verification
- Tensile Test
- Torque to Deform Test
- Axial Load Test
- Weld Integrity Test
- Outer Sheath Axial Load Test
- Radio-Detectability Test
- Corrosion Resistance Characterization
- Simulated Use Testing
- Dimensional Verification at 2 years
- Outer Sheath Axial Load Test at 2 years
- Simulated Use Test at 2 years

Sterilization

- Product adoption equivalency per AAMI TIR:28-2009

Biocompatibility:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- C3a Complement Activation
- SC5b-9 Complement Activation
- Direct Hemolysis
- Indirect Hemolysis
- Thrombosis – Partial Thromboplastin Time (PTT)
- Material Mediated Pyrogenicity

Preclinical and Clinical Data:
Preclinical and clinical data was not required to demonstrate substantial equivalence. The design characteristics of the subject device are similar to the predicate. The design verification and validation test results demonstrated that the subject device is as safe and clinically effective as the predicate device.

Substantial Equivalence
Based on the similarities in design between the subject and predicate devices, and the performance data, the TightRail Sub-C are substantially equivalent to the previously cleared versions of the TightRail and TightRail Mini (K142546 and K150360, respectively).

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