December 15, 2022

Spectranetics Inc.
Jordan Baum
Regulatory Affairs Specialist
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K223472
Trade/Device Name: TightRail Guardian Motorized Dilator Sheath, 9 French (575-009); TightRail Guardian Motorized Dilator Sheath, 11 French (575-011); TightRail Guardian Motorized Dilator Sheath, 13 French (575-013)
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: November 17, 2022
Received: November 17, 2022

Dear Jordan Baum:

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,

Hetal B. Patel -S

Hetal Odobasic
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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.

Submission Number *(if known)*

K223472

Device Name

TightRail Guardian Motorized Dilator Sheath, 9 French (575-009);
TightRail Guardian Motorized Dilator Sheath, 11 French (575-011);
TightRail Guardian Motorized Dilator Sheath, 13 French (575-013)

Indications for Use *(Describe)*

The TightRail Guardian motorized dilator sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads.

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 17 November 2022

510(k) Submitter / Holder:	Spectranetics 9965 Federal Drive Colorado Springs, CO 80921.3617 Establishment Registration No: 3007284006
Contact:	Mr. Jordan Baum Regulatory Affairs Specialist Mobile: (719) 247-0183 Fax: (719) 447-2070 Email: Jordan.Baum@philips.com

Subject Device

Device Trade Name:	TightRail Guardian Motorized Dilator Sheath
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:	575-009, 575-011, 575-013

Predicate Devices

The TightRail Guardian Motorized Dilator Sheath is being compared to the following legally marketed predicate devices:

TightRail Guardian Motorized Dilator Sheath

510(k) Number:	K212784 (cleared 24 August 2022)
Manufacturer:	The Spectranetics Corporation
Trade Name:	TightRail Guardian Motorized Dilator Sheath
Device Common Name:	Sheath

Intended and Indications for Use

The TightRail Guardian Motorized Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads.

Device Description

The TightRail Guardian motorized dilator sheath is a sterile, single use, prescription only device used for cardiac leads. The device is comprised of:

1. Drive Assembly

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

2. Dilation Extension Selection (DES) Assembly
3. Motor Drive Handle
4. Outer Sheath Accessory
5. Fish Tape Accessory

The motorized dilator sheath is advanced or retracted along the target lead to be removed. Pulling the trigger on the handle of the TightRail Guardian device results in activation of the motor and subsequent rotation of the inner shaft and cam blade. Trigger activation results in bidirectional rotation of the dilation mechanism. Actuation of the distal dilation mechanism causes dilation of tissue and fibrous attachments surrounding the lead targeted for removal, thereby facilitating removal of said lead. The device has two modes of operation, providing dilation with the blades shielded or extended. The diameter sizes range from 9 French (F) to 13 F. The nominal effective length of the TightRail Guardian is 47.5 cm. The outer sheath accessory may be used for additional support by creating a conduit for the device's shaft assembly. The outer sheath may also be used to maintain venous access for guidewire placement, prior to implantation of a new lead. The fish tape accessory may be used to feed a target lead and locking stylet through the inner lumen of the device.

Technological Characteristics

The TightRail Guardian device features a battery powered dilation mechanism and two dilation modes (Shielded, Extended). The dilation mechanism is activated through a trigger on the device handle. The shaft of the dilator sheath is designed from laser-cut stainless steel hypotubes to provide columnar stability during device advancement and actuation. The laser-cuts are progressively increased across the shaft, to provide additional flexibility toward the distal tip of the dilator sheath.

The TightRail Guardian Motorized Dilator Sheath features the same performance characteristics and overall design as the predicate device (K212784). There are no changes to the principle of operation and no changes to the intended use.

Performance Data

The following testing was conducted to validate and verify that the subject device met all specifications:

Design Verification and Validation Testing

- Simulated Use Testing
- Simulated Environment Testing
- Human Factors Evaluation
- Linear and Radial Dimensional Testing
- Device Weight Measurement
- Blade Extension Testing
- Atraumatic Surface Testing
- Axial Load Testing
- Tensile Testing
- Flexibility Testing
- Outer Sheath Compression Testing
- EMC/EMI and Electrical Medical Safety Testing
- Radiopacity Evaluation

Sterilization

- Product adoption equivalency per AAMI TIR28:2016

Biocompatibility

- Cytotoxicity
- Sensitization
- Irriation/Intracutaneous Reactivity
- Material Mediated Pyrogenicity
- Acute Systemic Toxicity
- Indirect and Direct Hemolysis
- Hemocompatibility

Pre-clinical 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 currently in use, and the performance data, the use of the TightRail Guardian device for the proposed indication does not raise new questions related to safety and effectiveness compared with the predicate. Therefore, TightRail Guardian is substantially equivalent to the TightRail Guardian device cleared under K212784.