December 23, 2020

The Spectranetics Corporation
Sondra Chandler
Regulatory Affairs Specialist
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K203540
Trade/Device Name: Bridge Occlusion Balloon
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: December 2, 2020
Received: December 3, 2020

Dear Sondra Chandler:

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,

for Carmen Gacchina Johnson, PhD
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K203540

Device Name
Bridge Occlusion Balloon

Indications for Use *(Describe)*
The Bridge Occlusion Balloon catheter is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage.

Any use for procedures other than those indicated in the instructions is not recommended.

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:

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*"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."*

# 510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92
Prepared on 02 December 2020

**510(k) Submitter / Holder:** Spectranetics
9965 Federal Drive
Colorado Springs, CO 80921-3617
Establishment Registration No: 3007284006

**Contact:** Sondra Chandler
Regulatory Specialist II
Office: 719-482-5909 Fax: 719.447.2040
Email: Sondra.chandler@philips.com

## Subject Device

Device Trade Name: Bridge Occlusion Balloon
Device Common Name: Catheter, Intravascular Occluding, Temporary
Device Class: II
Classification Regulation: 21 CFR 870.4450
Regulation Description: Vascular Clamp
Product Code: MJN
510(k) Type: Special
Model Numbers: 590-001

## Predicate Device

The subject device (Bridge Occlusion Balloon) was compared to the following legally marketed predicate device:
510(k) Number: K153530
Manufacturer: Spectranetics
Trade Name: Bridge Occlusion Balloon
Device Common Name: Catheter, Intravascular Occluding, Temporary
Model Numbers: 590-001

## Device Description

The Bridge Occlusion Balloon catheter is designed to be delivered percutaneously to the superior vena cava (SVC) for the purpose of providing occlusion of the SVC and providing emergency control of hemorrhage and perioperative occlusion in the event of an SVC tear or perforation during a lead extraction procedure.

The Bridge Occlusion Balloon catheter is constructed of a compliant polyurethane balloon mounted on a dual lumen polyurethane shaft.

The hub port, marked BALLOON, is connected to the balloon inflation lumen. The unmarked hub port is connected to the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire. A strain relief is mounted to the catheter shaft just distal of the proximal hub.

Three platinum-iridium radiopaque markers are placed within the balloon segment of the catheter to provide visual reference points for balloon positioning within the SVC prior to inflation.

**Intended and Indications for Use**
The Bridge Occlusion Balloon Catheter is indicated for use for temporary vessel occlusion of the superior vena cava in applications including perioperative occlusion and emergency control of hemorrhage.

Any use for procedures other than those indicated in the instructions is not recommended.

**Comparison of Technological Characteristics with the Predicate Device**
The Bridge Occlusion Balloon Catheter is deliverable to the target vasculature to perform occlusion procedures. The subject device is identical to the predicate device in terms of technological characteristics. There are labeling differences between the subject and predicate device. The subject device labeling includes a new warning regarding increased risk of thrombus with prolonged dwell times. The labeling also includes clarified workflows to reduce this risk.

The predicate device was cleared with a 6-month shelf-life which was subsequently extended to 2 years after clearance. The subject device shelf-life is identical to the current 2-year shelf-life of the predicate device.

The predicate device has undergone minor packaging changes after clearance. The tray and lid have minor dimensional changes. The header bag changed from Tyvek to Tyvek and Nylon. The predicate device now uses packaging wedges. The subject device packaging is identical to the current predicate device packaging.

**Performance Data**
The shelf-life extension and packaging changes are supported by test data demonstrating that the device and packaging adhere to the same acceptance criteria used in the predicate 510(k) after aging equivalent to 2 years.

**Design Verification and Validation Testing**
IFU Validation was performed.

**Preclinical and Clinical Data**
No preclinical or clinical data was needed to support this submission.

**Substantial Equivalence**
Based on the similarities in design between the subject and predicate devices, and the IFU validation, performed, the subject Bridge Occlusion Balloon is substantially equivalent to the previously cleared Bridge Occlusion Balloon (K153530).