



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 24, 2016

Spectranetics, Inc.
Mr. Christopher McLellan
Regulatory Affairs Manager
9965 Federal Drive
Colorado Springs, Colorado 80921

Re: K153530
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 8, 2015
Received: December 9, 2015

Dear Mr. McLellan:

This letter corrects our substantially equivalent letter of February 5, 2016.

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" (21CFR 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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153530

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.

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510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92(c)
Prepared on December 8, 2015.

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

Contact: Christopher McLellan
Regulatory Affairs Manager
Office: 719.447.2475
Mobile: 719.314.8561
Fax: 719.447.2040
Email: christopher.mclellan@spnc.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: Traditional
Model Number: 590-001

Predicate Device

The Bridge Occlusion Balloon was compared to the following legally marketed predicate device:

510(k) Number: K140273
Manufacturer: Boston Scientific
Trade Name: Equalizer Occlusion Balloon Catheter
Device Common Name: Catheter, Intravascular Occluding, Temporary

Device Description

The Bridge Occlusion Balloon 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 balloon mounted on a dual lumen shaft. This guidewire lumen is used to pass the catheter over a guidewire.

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 in applications including perioperative occlusion and emergency control of hemorrhage.

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

Technological Characteristics

The Bridge Occlusion Balloon is similar in design characteristics and performance to the predicate device. Similar to the predicate, the Bridge Occlusion Balloon is deliverable to the target vasculature and is appropriately sized to perform vascular occlusion procedures. The subject device includes vessel specificity (SVC) in its proposed indication, which differs from the predicate. Performance testing data, including preclinical animal studies have demonstrated that the Bridge Occlusion Balloon is substantially equivalent to the predicate device.

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 and Visual Tests
 - Crossing Profile, Balloon Working Length, Guidewire Compatibility, Catheter Effective Length, Surface Appearance, Distal Tip Configuration, Luer Compatibility
- Performance Testing
 - Deployment and Retraction, Inflation and Deflation Time, Balloon Bond Strength, Inflated Balloon Size Stability, Tip Bond Strength, Hub Bond Strength, Flexibility and Kink, Leak Testing, Balloon Burst Volume, Device Fatigue

Sterilization

- Half Cycle Validation per ISO 11135

Biocompatibility:

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

Preclinical and Clinical Data:

Preclinical data were gathered to demonstrate substantial equivalence of the Bridge Occlusion Balloon when used as intended. The preclinical GLP testing demonstrated

that the Bridge Occlusion Balloon meets its intended use of SVC occlusion. No clinical testing was required for the Bridge Occlusion Balloon.

Substantial Equivalence

Based on the similarities in design between the subject and predicate devices, and the performance data, the Bridge Occlusion Balloon is substantially equivalent to the legally marketed Equalizer Occlusion Balloon Catheter.