June 8, 2018

Embolyx, Inc

% Dave Yungvirt

Third Party Review Group, LLC

The Old Station House

24 Lackawanna Place

Millburn, New Jersey 07041

Re:  K180904

Trade/Device Name: Sniper Infusion Catheter with Balloon Occlusion
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: MJN
Dated: May 22, 2018
Received: May 24, 2018

Dear Dave Yungvirt:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

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

Enclosure
Device Name
Sniper Infusion Catheter with Balloon Occlusion

Indications for Use (Describe)
Sniper Infusion Catheter with Balloon Occlusion is intended for use in the blood vessels of the peripheral vasculature where temporary occlusion is desired and offers vessel selective technique of temporary vascular occlusion for selectively stopping or controlling blood flow. The Sniper Infusion Catheter with Balloon Occlusion is also intended to assist in the delivery of diagnostic agents such as contrast media and therapeutic agents into the peripheral vasculature.

Type of Use (Select one or both, as applicable)

- [X] 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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“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.”
Sniper Infusion Catheter with Balloon Occlusion
Traditional Premarket Notification K180904

510(k) Summary

I. SUBMITTER
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II. DEVICE
Name of Device: Sniper Infusion Catheter with Balloon Occlusion
Common or Usual Name: Catheter, Intravascular Occluding, Temporary
Classification Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN

III. PREDICATE DEVICE
Embolx Occlusion Balloon Catheter, K142692
This predicate has not been subject of a design related recall.

IV. DEVICE DESCRIPTION
The Sniper® Infusion Catheter with Balloon Occlusion is a coaxial dual lumen catheter with an occlusion balloon located at the distal end to provide temporary complete occlusion or limitation of blood flow in peripheral blood vessels as well as provide a delivery conduit for diagnostic agents such as contrast media and therapeutic agents such as embolization particles into the peripheral vasculature. One lumen is dedicated to balloon inflation and deflation, the other lumen is intended to accommodate the guide wire and delivery of fluids and other diagnostic and therapeutic agents. Device placement in the target location is achieved using a guiding catheter that has been placed through an introducer. A guidewire is threaded through the device’s lumen for navigating the device to the selected vessel location. Device visualization is provided by two radiopaque bands using fluoroscopy. One radiopaque band is located on the distal tip of the device, and one on the distal end of the balloon, which is 1 cm proximal to the distal tip. Through the guidewire (perfusion) lumen, the clinician can deliver diagnostic or therapeutic agents into the selected blood vessel. After treatment, the balloon is deflated and blood flow resumes.
The proximal hub consists of two ports: one port for use by the guidewire and delivery of fluids and the second port for inflation and deflation of the balloon. The low profile balloon is manufactured of a compliant material that allows ease of insertion and withdrawal from the vasculature and conforms to the vessel wall. The balloon is inflated and deflated with a hand held syringe. The device is supplied sterile by ETO and is intended for single use.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Sniper® Infusion Catheter with Balloon Occlusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion Lumen</td>
<td>0.020” ID</td>
</tr>
<tr>
<td>Infusion Pressure</td>
<td>Up to 900psi</td>
</tr>
<tr>
<td>Functional Length</td>
<td>110 cm or 130 cm or 150 cm</td>
</tr>
<tr>
<td>Rated Outer Diameter</td>
<td>0.038”</td>
</tr>
<tr>
<td>Shelf life</td>
<td>1 year</td>
</tr>
<tr>
<td>Balloon diameter</td>
<td>Up to 6mm</td>
</tr>
</tbody>
</table>

The following accessories are included in the sterile package with the device:
- Balloon aspiration syringe (10mL)
- Balloon inflation syringe (0.25mL)
- 1-way valve

V. INDICATIONS FOR USE

Sniper® Infusion Catheter with Balloon Occlusion is intended for use in the blood vessels of the peripheral vasculature where temporary occlusion is desired and offers vessel selective technique of temporary vascular occlusion for selectively stopping or controlling blood flow. The Sniper® Infusion Catheter with Balloon Occlusion is also intended to assist in the delivery of diagnostic agents such as contrast media and therapeutic agents into the peripheral vasculature.

The indications for use statement for the Sniper Infusion Catheter with Balloon Occlusion is identical to the predicate device. Both devices have the same intended use in the blood vessels of the peripheral vasculature for temporary vascular occlusion and delivery of diagnostic agents.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and the predicate devices are based on the same technological principles for providing temporary complete vascular occlusion and delivery of therapeutic and diagnostic agents in the peripheral vasculature. Both devices have the following identical technological characteristics:

- Guidewire guided catheter advanced through an introducer sheath in the peripheral vasculature.
- Dual lumen coaxial design with proximal hub consisting of two ports; one port for use by the guidewire and delivery of fluids and the second port for inflation and deflation of the balloon.
- Occlusion balloon at the distal end with two embedded radiopaque bands to allow for visualization under fluoroscopic guidance.
The following technological differences exist between the subject and predicate devices:

- The inflation and burst volume of the occlusion balloon has increased to accommodate slightly larger vessel sizes.
- Strain relief is longer to provide added flexibility and protection to the proximal aspect of the catheter.
- Additional functional lengths (130cm and 150cm) have been added to accommodate current clinical practices.
- Hub material changed to nylon to improve chemical stability over long-term use.
- The occlusion balloon material has been changed to provide higher tensile strength and elongation percentage.
- Hydrophilic coating has been changed to improve lubricity.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the Sniper® Infusion Catheter with Balloon Occlusion demonstrates that the device is in compliance with ISO 10993-1:2009 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”, as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- ISO Intracutaneous Study - Extract
- ISO Systemic Toxicity
- Sensitization
- Pyrogen Study - Material Mediated
- ASTM Hemolysis
- SC5b-9 Complement Activation Assay
- In Vivo Thromboresistance Study - Jugular Vein

The Sniper® Infusion Catheter with Balloon Occlusion is considered tissue contacting for a duration of less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing does not apply to the subject device.

Software Verification and Validation Testing

Software verification and validation testing does not apply to the subject device.
Performance Testing
The performance test evaluation for the Sniper® Infusion Catheter with Balloon Occlusion demonstrates that the device is in compliance with ISO 10555-1:2013 “Sterile, single-use intravascular catheters - Part 1: General requirements” and ISO 10555-4:2013 “Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters.” The battery of testing included the following tests:

- Dimensional Verification
- Balloon Rated Burst Volume
- Balloon Fatigue (Repeat Balloon Inflations)
- Balloon Compliance (Diameter v. Volume)
- Balloon Preparation, Deployment and Retraction (Time/Position)
- Catheter Bond Strength and Tip Pull Test
- Flexibility and Kink Test (Bend/Buckle)
- Torque Strength Test (Torsional stress)
- Radiopacity
- Coating Integrity
- Particulate Matter Analysis
- Catheter Body Leakage & Burst Test
- Power Injection and Contrast Media Flow Rate
- Corrosion Resistance
- Lipiodol Compatibility
- Shipping
- Shelf-life & Accelerated Aging
- Sterilization

The non-clinical data support the safety of the device and demonstrate that the Sniper Infusion Catheter with Balloon Occlusion performs comparably to the predicate device that is currently marketed for the same intended use.

Animal Study
No animal testing was required to support this 510(k) as the indications for use and technology are equivalent to those of the predicate device.

Clinical Studies
No clinical testing was required to support this 510(k) as the indications for use and technology are equivalent to those of the predicate device.

VIII. CONCLUSIONS
The Sniper Infusion Catheter with Balloon Occlusion was found to be substantially equivalent to the predicate device.