May 20, 2020

Infinity Angioplasty Balloon Company, LLC
Ms. Tiffini Wittwer
Regulatory Affairs
6865 N. Reynolds Rd Suite 200
Toledo, Ohio 43615

Re: K192399

Trade/Device Name: Infinity Angioplasty Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: April 13, 2020
Received: April 15, 2020

Dear Ms. Wittwer:

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/combo-p/); 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.


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,

Sara M. Royce -S

For Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K192399

Device Name
INFINITY Angioplasty Balloon Catheter

Indications for Use (Describe)
The INFINITY Angioplasty Balloon Catheter™ is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary or cerebrovascular arteries.

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.

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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

“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 K192399

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<thead>
<tr>
<th><strong>Submitter:</strong></th>
<th>INFINITY Angioplasty Balloon Company, LLC</th>
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</table>
| **Contact Person:** | Tiffini Wittwer  
Regulatory Affairs  
Phone: 707.799.6732  
E-mail: twittwer@mededge.io |
| **Trade Name:** | INFINITY Angioplasty Balloon Catheter |
| **Common Name:** | Percutaneous catheter |
| **Classification:** | Class II |
| **Product Code:** | LIT |
| **Regulation:** | 21 CFR 870.1250 |
| **Predicate Device(s):** | The subject device is substantially equivalent to the following device:  
• Boston Scientific Corporation Sterling Over-the-Wire PTA Balloon Catheter (K141112) |
| **Device Description:** | The INFINITY Angioplasty Balloon Catheter is an intravascular angioplasty balloon catheter with a retractable sheath allowing a variable length inflatable balloon; up to 250mm. The over the wire (OTW) catheter has a retractable sheath allowing the balloon to be inflated at various lengths as determined by the physician. The balloon lengths are graduated with radiopaque marker bands denoting 0mm, 100mm, 200mm, and 250mm. The INFINITY Balloon Catheter is a 6Fr catheter system with a shaft working length of 150cm. The device uses a semi-compliant balloon with a rated burst pressure of 15atm and an indicated clinical use range of 4atm – 12atm. The balloon expands to a nominal diameter of 5.0 to 5.5mm. |
| **Indication for Use:** | The INFINITY Angioplasty Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary or cerebrovascular arteries. |
**Premarket Notification for the INFINITY Angioplasty Balloon Catheter™**

<table>
<thead>
<tr>
<th><strong>510(k) Number</strong></th>
<th>K192399</th>
<th>K141112</th>
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<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td>INFINITY Angioplasty Balloon Co., LLC</td>
<td>Boston Scientific Corporation</td>
</tr>
<tr>
<td><strong>Classification</strong></td>
<td>Class II</td>
<td>Class II</td>
</tr>
<tr>
<td><strong>Product Code</strong></td>
<td>LIT</td>
<td>LIT</td>
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<td><strong>Regulation</strong></td>
<td>21 CFR 870.1250</td>
<td>21 CFR 870.1250</td>
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**Indications for Use**

- **Subject device**
  - The INFINITY Angioplasty Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This catheter is not for use in coronary or cerebrovascular arteries.
- **Predicate device**
  - The Sterling OTW PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature.

  - Subject device has narrower indication for use than the predicate. This difference limits use of the device compared to the predicate and does not raise new questions of safety or effectiveness.

**Principle of operation**

- Inflation of semi-compliant balloon for dilation
- Same

**Balloon Diameter (mm)**

- Subject device: 5.0
- Predicate device: 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0

  - Same as one predicate device size

**Balloon Length (mm)**

- Subject device: Variable
  - Marker bands located at 100mm, 200mm, and 250mm on balloon length
- Predicate device: 20, 30, 40, 60, 80, 100, 200, 220

  - Dimensional testing, simulated use, rated burst pressure, and in vivo testing demonstrates the difference does not create additional risk to safety and effectiveness of the subject device.

**Balloon Length Variability**

- Subject device: Yes
- Predicate device: No 1 fixed balloon length per device size

  - Simulated use and in vivo testing demonstrate the
<table>
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<tr>
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<th>Balloon length controlled by outer sheath placement relative distal tip of the balloon.</th>
<th>difference does not create additional risk to safety and effectiveness of the subject device</th>
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<tbody>
<tr>
<td><strong>Outer Sheath</strong></td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td><strong>Number of radiopaque markerbands</strong></td>
<td>5 Proximal and distal ends of balloon, 100mm and 200mm balloon length, and distal tip of outer sheath</td>
<td>2 Proximal and distal ends of balloon</td>
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<td>Visibility, marker band to balloon alignment, and <em>in vivo</em> testing demonstrate the difference does not create additional risk to safety and effectiveness of the subject device</td>
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<td><strong>Location markers</strong></td>
<td>Yes Markers designate location of the sheath relative to the catheter shaft</td>
<td>Markers designate locations on catheter tip to the guiding catheter</td>
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<td>Marker band to balloon alignment, and simulated use demonstrate the difference does not create additional risk to safety and effectiveness of the subject device</td>
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<tr>
<td><strong>Catheter Shaft Lengths (cm)</strong></td>
<td>150</td>
<td>40, 90, 135, 150</td>
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<tr>
<td><strong>Guidewire compatibility</strong></td>
<td>0.018”</td>
<td>0.014”, 0.018”</td>
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<tr>
<td><strong>Sterilization Method</strong></td>
<td>Ethylene Oxide</td>
<td>Ethylene Oxide</td>
</tr>
<tr>
<td></td>
<td>Same</td>
<td>Same</td>
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### Functional Testing:
To verify that the device design meets its functional and performance requirements, representative samples of the device underwent performance bench testing and pre-clinical animal testing. As a result of verification and validation activities and risk assessment, testing ensures the device design meets its functional and performance requirements. The following tests were performed:

- Balloon compliance
- Balloon nominal diameter
- Balloon length
- Balloon Fatigue
- Marker band visibility
- Inflation and deflation time
- Device tracking, delivery, and retrieval
- Torque strength
- Kink resistance
- Joint strength testing
- Rated burst pressure
- Simulated use

The following standards were used in testing:

- ISO 11135:2018, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-1:2018, Biological evaluation of medical devices

### Conclusion:
The INFINITY Angioplasty Balloon Catheter™ intended use, indication for use, materials, and fundamental scientific technology is similar to the predicate device. Performance bench testing and pre-clinical testing demonstrate that the differences between the subject device and the predicate device do not raise new risks of safety and effectiveness.