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/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 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

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)*
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)*

☒ 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 K192399

Submitter:	INFINITY Angioplasty Balloon Company, LLC
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 a 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.

	INFINITY Angioplasty Balloon Catheter (Subject Device)	Boston Scientific Corporation Sterling™ Over-the-Wire PTA Balloon Dilation Catheter (Predicate Device)	Comment
510(k) Number	K192399	K141112	
Manufacturer	INFINITY Angioplasty Balloon Co., LLC	Boston Scientific Corporation	
Classification	Class II	Class II	Same
Product Code	LIT	LIT	Same
Regulation	21 CFR 870.1250	21 CFR 870.1250	Same
Indications 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.	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	Inflation of semi-compliant balloon for dilation	Same
Balloon Diameter (mm)	5.0	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)	Variable Marker bands located at 100mm, 200mm, and 250mm on balloon length	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	Yes	No 1 fixed balloon length per device size	Simulated use and *in vivo* testing demonstrate the

	Balloon length controlled by outer sheath placement relative distal tip of the balloon.		difference does not create additional risk to safety and effectiveness of the subject device
Outer Sheath	Yes	Yes	Same
Number of radiopaque markerbands	5 Proximal and distal ends of balloon, 100mm and 200mm balloon length, and distal tip of outer sheath	2 Proximal and distal ends of balloon	Visibility, marker band to balloon alignment, and *in vivo* testing demonstrate the difference does not create additional risk to safety and effectiveness of the subject device
Location markers	Yes Markers designate location of the sheath relative to the catheter shaft	Markers designate locations on catheter tip to the guiding catheter	Marker band to balloon alignment, and simulated use demonstrate the difference does not create additional risk to safety and effectiveness of the subject device
Catheter Shaft Lengths (cm)	150	40, 90, 135, 150	Same
Guidewire compatibility	0.018”	0.014”, 0.018”	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same

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 • ISO 10555:2018, Intravascular catheters – Sterile and single use intravascular catheters.
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.