September 15, 2020

Boston Scientific Corporation
Jennifer Mrkvicka
Regulatory Affairs Specialist
3 Scimed Place
Maple Grove, Minnesota 55311

Re: K201170
Trade/Device Name: Athletis™ PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: September 2, 2020
Received: September 3, 2020

Dear Jennifer Mrkvicka:

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,

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)*
K201170

Device Name
Athletis™ PTA Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Athletis™ PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature including upper extremity, renal, iliac, and infrainguinal vessels and the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

The Athletis™ PTA Balloon Dilatation Catheter is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature.

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
Per 21 CFR §807.92

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Jennifer Mrkvicka Regulatory Affairs Specialist 3 Scimed Place Maple Grove, MN 55311-1566 Phone: 763-255-0917 Fax: 763-494-2222 e-mail: Jennifer.Mrkvicka@bsci.com
Date Prepared	30 April 2020
Proprietary Name	Athletis™ PTA Balloon Dilatation Catheter
Common Name	PTA Balloon Dilatation Catheter
Product Code	LIT
Classification	Class II, 21 CFR Part 870.1250
Predicate Device	Mustang Balloon Dilatation Catheter (K103751), cleared 22 March 2011
Reference Devices	Gladiator PTA Balloon Dilatation Catheter (K113681), cleared 11 January 2012 Bard Conquest (K083657), cleared 24 December 2008 Bard Conquest 40 (K120660), cleared 15 March 2012
Device Description	The Athletis™ Percutaneous Transluminal Angioplasty (PTA) Balloon Dilatation Catheter is an over-the-wire (OTW), non-compliant, high performance balloon catheter for peripheral indications. The catheter is compatible with 0.035 in (0.89 mm) guidewires. The Athletis™ PTA Balloon Dilatation Catheter features a dual lumen shaft ending in a Y-connector manifold with luer lock fittings. The manifold port marked “WIRE” is used to deliver the catheter over a 0.035 in (0.89 mm) guidewire. The manifold port marked “BALLOON” is used to inflate and deflate the balloon during the procedure. Two radiopaque marker bands, in conjunction with fluoroscopy, aid in the visualization of the balloon. A lubricious hydrophobic coating is applied from the distal tip to just proximal of the balloon to assist with delivery of the device. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the treatment site. The working lengths of the balloon catheter are 50 cm, 75 cm and 135 cm to allow device selection for various anatomies.
Intended Use of Device	The Athletis™ PTA Balloon Dilatation Catheter is intended to be used to treat resistant lesions in the peripheral vasculature.
Indications for Use	The Athletis™ PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature including upper extremity, renal, iliac, and infrainguinal vessels and the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Athletis™ PTA Balloon Dilatation Catheter is also indicated for post-dilatation of stents and stent grafts in the peripheral vasculature.
Comparison of Technological Characteristics	The Athletis™ PTA Balloon Dilatation Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Mustang™ Balloon Dilatation Catheter (K103751).

Comparison to predicate device Mustang in Materials and Manufacturing

Characteristic	Comment
Manifold	Similar material and design serving same function.
Pinch-off Tube	Similar material and design serving same function.
Strain Relief	Identical base resin and similar colorant serving same function.
Proximal Dual Lumen Shaft	Similar material and same design serving same function.
Distal Guidewire Lumen Shaft	Identical
Bumper Tip	Identical base resin and similar colorant serving same function.
Balloon	Difference in design but serving same function and intended use.
Balloon Bonding Method	Identical
Markerbands	Identical
Coating	Identical
Balloon Protector	Identical
Sterilization Method	Identical
SAL	Identical
Packaging	Identical design and materials for coiled configuration. Mustang does not use a straight configuration.
Nominal Balloon Diameters	Similar range serving same function and intended use.
Balloon lengths	Similar range serving same function and intended use.
Rated Burst Pressure (RBP)	Athletis is a higher pressure balloon than Mustang. Balloon construction is a factor. All Athletis balloon diameters were tested and demonstrate with 95% confidence that 99.9% of devices will not burst at or below the rated burst pressure.
Effective Lengths	Similar ranges serving same function and intended use.
Recommended Introducer Sheath Compatibility	Similar ranges serving same function and intended use.
Recommended Guidewire	Identical compatibility.

Performance Data

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

The following biocompatibility tests were completed on the Athletis™ PTA Balloon Dilatation Catheter:

Cytotoxicity	Direct Contact Hemolysis

Sensitization	Complement Activation
Intracutaneous Reactivity	In Vitro Hemocompatiblity
Acute Systemic Toxicity	Ames Mutagenincity
Materials Mediated Pyrogenicity	Mouse lymphoma Assays
USP Physicochemical	

The following *in vitro* performance tests were completed for the Athletis™ Balloon Dilatation Catheter:

Working Length	Device Tensile (including Tip Tensile)
Shaft Outer Diameter	Balloon Protector Removal Force
Balloon Crossing Profile	Shaft Kink Resistance
Preparation, Deployment, and Retraction	Torque Strength
Balloon Rated Burst Pressure and Burst in Stent	Radiopacity
Balloon Fatigue/Fatigue in Stent	Guidewire Compatibility
Balloon Compliance and OD at nominal	Sheath Insertion and Withdrawal Force
Balloon Inflation/Deflation Time	Coating Integrity
Particulate Evaluation	Particulate in Stent

The Athletis™ PTA Balloon Dilatation Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010. Bench, animal and biocompatibility testing in accordance with ISO 10993 were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing; therefore, this device may be considered substantially equivalent to the predicate device.

GLP Summary	An Acute GLP Animal Study (porcine) was conducted to evaluate *in vivo* thrombogenicity and acute performance and safety of the Athletis™ PTA Balloon Dilatation Catheter. The study provides evidence that the Athletis™ PTA Balloon Dilatation Catheter test articles, regardless of size, were usable, non-thrombogenic, and did not raise any new questions of safety in the arteries and veins of the porcine peripheral vasculature model. Therefore, this device may be considered substantially equivalent to the predicate device.

Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the Athletis™ PTA Balloon Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Mustang™ Balloon Dilatation Catheter (K103751).