DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 30, 2017

Boston Scientific Corporation
Lori Berends
Sr. Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, MN 55311-1566

Re: K171612
Trade/Device Name: ACUITY™ Pro Lead Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 31, 2017
Received: June 1, 2017

Dear Lori Berends:

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" (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 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,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171612

Device Name
ACUITY™ Pro Lead Delivery System

Indications for Use *(Describe)*
The ACUITY™ Pro Lead Delivery System is intended to access the coronary venous system, and may be used alone (9F) or in a dual catheter delivery (9F with 7F). The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary for K171612

Per 21 CFR §807.92

Common or Usual Name	Percutaneous Guide Catheter
Trade Name(s)	ACUITY™ Pro Lead Delivery System
Product Code	DQY – Percutaneous Catheter
Classification of Device	Class II (special controls) - 21 CFR 870.1250
Submitter's Name and Address	Boston Scientific Corporation Three Scimed Place Maple Grove, MN 55311-1566
Contact Name and Information	Lori Berends Sr. Regulatory Affairs Specialist Phone: 763-494-1528 Fax: 763-494-2222 Email: Lori.Berends@bsci.com
Date Prepared	26 May 2017
Section 514 of the Act Performance Standards	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for percutaneous catheters.
Establishment Registration Numbers	**Owner /Operator:** Boston Scientific Corporation 300 Boston Scientific Way Marlborough, MA 01752 USA ERN: 9912058
	Manufacturing Facility: Boston Scientific Corporation Two Scimed Place Maple Grove, MN 55311 USA ERN: 2134265

Sterilization Facilities:	BSC Coventry 8 Industrial Drive Coventry, RI 02816 USA ERN: 1000121056 Steris Isomedix 3459 South Clinton Ave South Plainsfield, NJ 07080 USA ERN: 2246552 Synergy Health Ireland, LTD IDA Business and Technology Park Sragh, Tullamore Co. Offaly Ireland ERN: 3002807314 Synergy Health AST, Venlo Faunalaan 38 Venlo Limburg, 5928 RZ Netherlands ERN: 3009337401 Synergy Health AST, SRL B13.1 Street 4, Avenue 1 El Coyol Free Zone El Coyol Alajeula 20102 Costa Rica ERN: 3010273872
Predicate Device	K132914 – ACUITY™ Pro Lead Delivery System Cleared on 03 April 2014
Device Description	The ACUITY™ Pro Lead Delivery System is designed for venous use to aid in the selective placement of cardiac resynchronization therapy (CRT) implantable venous leads in the cardiac vasculature. The catheter shafts are comprised of a PTFE inner liner, a reinforcing layer of stainless steel braid, and an outer polymer jacket. The distal end has a radiopaque polymer tip, while the proximal end has a hub with flush luer fitting to allow flush, contrast injection and aspiration polymer . The approximate working lengths of the catheters are 45-54cm for the 9F design and 60-69 cm for the 7F design. The ACUITY Pro 9F is provided with the following accessories: 0.014 inch guidewire torquer, 0.014 inch guidewire introducer, ACUITY™ Universal Cutter, two transvalve introducer tools, and a venous access dilator
Intended Use/ Indications for Use	The ACUITY™ Pro Lead Delivery System is intended to access the coronary venous system, and may be used alone (9F) or in a dual catheter delivery (9F with 7F). The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

Comparison of Technological Characteristics	The proposed ACUITY™ Pro Lead Delivery System is substantially equivalent to the existing ACUITY™ Pro Lead Delivery System cleared under premarket notification K132914 on 03 April 2014. The ACUITY™ Pro Lead Delivery System has the same intended use, scientific technology, design (with the exception of the hub seal design), materials (with the exception of the hub seal material), sterilization method, and packaging materials as the applicable predicate device.
Summary of Non-Clinical Test Summary	Bench testing was performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device with the modified hub seal 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 device testing. The following performance tests were completed on the ACUITY™ Pro Lead Delivery System to verify that the modified device continues to meet the specification requirements impacted by the design change as well as meet the new product specification requirement for air aspiration: • Ancillary Device Passage through Valve • 7F Catheter Passage through 9F Valve • Hub Valve Hemostasis/Static Leak • Air Aspiration The following usability tests were completed on the ACUITY™ Pro Lead Delivery System to ensure that the modified device continues to meet all user requirements as part of a lead delivery system: • Catheter provides a conduit/back-up support for other devices to pass • Catheter is able to be removed by cutting The following chemical characterization tests were completed on the ACUITY™ Pro Lead Delivery System to provide evidence that the extractable species in the proposed hub seal material and process do not pose an increased chemical safety risk when compared to the predicate seal material: • Volatile/Semi-volatile organic compounds observed by GC-MS • Non-volatile organic compounds observed by LC-MS
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the proposed ACUITY™ Pro Lead Delivery System with the modified hub seal has been shown to be appropriate for its intended use and is considered to be substantially equivalent to its predicate (K132914).