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

March 23, 2017

Boston Scientific Corporation
Nikki Wahlberg
Sr. Regulatory Affairs Specialist
Two Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K163314
Trade/Device Name: Guidezilla™ II Guide Extension Catheter;
Guidezilla™ II LONG Guide Extension Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 17, 2017
Received: February 21, 2017

Dear Ms. Wahlberg:

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,

Fernando Aguel -S

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)*

K163314

Device Name
Guidezilla™ II Guide Extension Catheter
Guidezilla™ II LONG Guide Extension Catheter

Indications for Use *(Describe)*

The Guidezilla II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

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	Nikki M Wahlberg Two Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-2381 Fax: 763-494-2981 e-mail: Nikki.Wahlberg@bsci.com		
Prepared	22 November 2016		
Proprietary Name	Guidezilla™ II Guide Extension Catheter Guidezilla™ II LONG Guide Extension Catheter		
Common Name	Guide Catheter		
Product Code	DQY		
Classification	Class II, 21 CFR Part 870.1250		
Primary Predicate Device	Guidezilla™ Guide Extension Catheter	K123765	19 March 2013
Reference Device(s)	GuideLiner V2 Catheter	K112082	01 December 2011
	GuideLiner XL Catheter	K091750	04 November 2009

Device Description

The Boston Scientific Guidezilla™ II and Guidezilla™ II LONG Guide Extension Catheters act as extensions to traditional guide catheters. The Guidezilla II Guide Extension Catheter enters through the parent guide catheter and extends an additional 15 cm out the distal end of the parent guide catheter, providing physicians with additional support to advance interventional devices into the vasculature. The Guidezilla II Guide Extension Catheter consists of a proximal stainless steel hypotube, which includes a handle used for device identification, and a distal guide catheter segment (25 cm or 40 cm) through which interventional devices may be delivered. The proximal hypotube is connected to the distal guide catheter segment by a small collar. The collar is made of radiopaque platinum iridium material that provides support and a smooth transition from the offset hypotube to the distal guide catheter segment. The distal guide catheter segment incorporates one radiopaque marker band located 2 mm from the distal tip of the device. The radiopaque collar and marker band aid in positioning the device during the procedure. A hydrophilic coating is applied to the distal 20 cm of the device.

Indications for Use / Intended Use Guide Wire

The Guidezilla™ II Guide Extension Catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.

Comparison of Technological Characteristics

The Guidezilla™ II and Guidezilla™ II LONG Guide Extension Catheter incorporates substantially equivalent design, packaging, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the predicate, Guidezilla™ Guide Extension Catheter K123765.

Performance Data

Design verification testing was performed to support a determination of substantial equivalence according to *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters,* September 2010. Guidezilla II also conforms to relevant sections of *EN ISO 10555-1: 2013, Sterile, single-use intravascular catheters; Part 1: General Requirements*. The results of the tests provide reasonable assurance that the proposed devices have 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 device performance tests were completed:

- Corrosion Resistance
- Average Outer Diameter
- Device Length
- Deliverability
- Tip Deflection
- Full Unit Tensile
- Post-Radius Tensile
- Radiopacity
- Proximal Markers
- Tracking an Interventional Device Through Guidezilla
- Withdrawing an Interventional Device Through Guidezilla
- Minimum Inner Diameter
- Entering an Interventional Device into Guidezilla
- Dye Flow
- Withdrawal of Guidezilla Device
- Particulates
- Torque
- Coating Integrity
- Kink Resistance

The following package performance tests were completed:

- Pouch Seal Strength
- Shelf Carton Condition
- Label Adhesion and Print Quality
- Master Shipping Carton/Condition
- Sterile Barrier Integrity
- Visual Sterile Barrier Integrity
- Device Removal from Carrier Tube

The following biocompatibility tests were completed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Complement Activation C3a and SC5b-9
- Materials Mediated Pyrogenicity
- Hemolysis Direct Contact
- Hemolysis Extract Method
- In Vivo Thrombogencity

Clinical Testing

Clinical evaluation was not required for this device.

Conclusion

Based on the indications for use, technological characteristics, safety and performance testing, the Guidezilla™ II and Guidezilla™ II LONG Guide Extension Catheters are appropriate for the stated intended uses and are considered to be substantially equivalent to the Guidezilla™ Guide Extension Catheter K123765.