Traditional 510(k) Submission
GUIDEZILLA™ Guide Extension Catheter

MAR 19 2013

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Holly Ramirez Phone: 763-494-2113 Fax: 763-494-2222 e-mail: Holly.Holmes@BSCI.com
Prepared	06 December 2012
Proprietary Name	GUIDEZILLA™ Guide Extension Catheter
Common Name	Guide Catheter
Product Code	DQY
Classification	Class II, 21 CFR Part 870.1250
Predicate Devices	GuideLiner® V2 Catheter K112082 01 December 2011
Device Description	The Boston Scientific GUIDEZILLA™ Guide Extension Catheter acts as an extension to a traditional guide catheter. GUIDEZILLA consists of a proximal stainless steel hypotube with a tab used for device identification and a distal guide catheter segment through which interventional devices may be delivered. The guide catheter segment incorporates two radiopaque marker bands to aid in positioning the device during the procedure. A hydrophilic coating is applied to the distal polymer segment of the device. GUIDEZILLA is a 5F catheter compatible with a 6F guide catheter. The effective length of the device is 145 cm.
Intended Use / Indications for Use	The GUIDEZILLA™ 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™ Guide Extension Catheter incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as the GuideLiner® V2 (K112082).

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 GUIDEZILLA™ Guide Extension Catheter:

Cytotoxicity	Direct Contact Hemolysis
Sensitization	Hemolysis Extract
Intracutaneous Reactivity	Complement Activation
Acute Systemic Toxicity	Partial Thromboplastin Time
Materials Mediated Pyrogenicity	In Vitro Hemocompatibility
USP Physicochemical	Latex

The following in-vitro performance tests were completed of the GUIDEZILLA™ Guide Extension Catheter:

Effective Length	Radiopacity
Outer Diameter	Dye Flow
Inner Diameter	Coating Integrity
Full Unit Tensile	Particulate Evaluation
Kink Resistance	Corrosion Resistance
Tip Deflection	Device Compatibility
Torque Strength	Packaging Integrity

Clinical Testing

Clinical Evaluation was not required for these devices.

Conclusion

Based on the indications for use, technological characteristics, and safety and performance testing, the GUIDEZILLA™ Guide Extension Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the GuideLiner® V2 (K112082).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 19, 2013

Boston Scientific Corporation
C/O Holly Ramirez
One Scimed Place
Maple Grove, MN 55311

Re: K123765
Trade/Device Name: Guidezilla™ Guide Extension Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 15, 2013
Received: February 19, 2013

Dear Ms. Ramirez:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Matthew G. Hillebrenner

for Bram Zuckerman, M.D.
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123765

Device Name: GUIDEZILLA™ Guide Extension Catheter

Indications for Use:

The Guidezilla 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.

Prescription Use ____X___
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G Hillebrenner