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

May 16, 2017

Boston Scientific Corporation
Ms. Liz Johnston
Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, MN 55311

Re: K163701
Trade/Device Name: Direxion and Direxion HI-FLO Torqueable Microcatheters
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: April 17, 2017
Received: April 18, 2017

Dear Ms. Johnston:

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)*
K163701

Device Name
Direxion and Direxion HI-FLO Torqueable Microcatheters

Indications for Use *(Describe)*
The Direxion and Direxion HI-FLO Torqueable Microcatheters are intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K163701
510(k) Summary

Per 21 CFR 807.92

Submitter's Name and Address	Boston Scientific Corporation Three Scimed Place Maple Grove, MN 55311 USA
Contract Information	Liz Johnston Regulatory Affairs Specialist Phone 763-494-1676 Fax: 763-494-2222 Email: Liz.Johnston@bsci.com
Date Prepared	22 December 2016
Proprietary Name	**Single Product Configurations:** • Direxion™ Torqueable Microcatheter • Direxion™ HI-FLO™ Torqueable Microcatheter **Preloaded Guidewire System Configurations:** • Direxion™ Fathom™-16 System Pre-Loaded Torqueable Microcatheter • Direxion™ Transend™-14 System Pre-Loaded Torqueable Microcatheter • Direxion™ HI-FLO™ Fathom™-16 System Pre-Loaded Torqueable Microcatheter • Direxion™ HI-FLO™ Transend™-18 System Pre-Loaded Torqueable Microcatheter
Common Name	Continuous Flush Catheters
Classification	Class II per CFR 870.1210
Predicate Device	Boston Scientific Direxion Microcatheters: • K142259, KRA, September 10, 2014

Device Description

The Direxion Microcatheter is available in small and large lumens. The Direxion Torqueable Microcatheter (Direxion) is a small lumen microcatheter with a distal outside diameter of 2.5F (0.85 mm), and a maximum outside diameter of 2.7F (0.95 mm). It has an inside diameter of 0.021 in (0.5 mm) minimally in the proximal and distal regions. The microcatheter lumen is able to accommodate steerable guidewires with diameters ≤ 0.018 in (0.47 mm).

The Direxion HI-FLO Torqueable Microcatheter (Direxion HI-FLO) is a large lumen microcatheter with a distal outside diameter of 2.9F (1.00 mm), and a maximum outside diameter of 3F (1.05 mm). It has an inside diameter of 0.027 in (0.6 mm) minimally in the proximal and distal regions. The microcatheter lumen is able to accommodate steerable guidewires with diameters ≤ 0.021 in (0.53 mm).

The Direxion and Direxion HI-FLO Microcatheters are available in a variety of tip shapes (Straight, Bern, Swan, and J) to aid with accessing challenging anatomy. The distal outer surface of the microcatheter is coated with a hydrophilic coating. A radiopaque marker is located at the distal tip to facilitate fluoroscopic visualization. Some Direxion Microcatheters have a second marker 3 cm proximal to the first marker. The distal tip of the microcatheter is steam shapeable. The proximal end incorporates a standard luer with rotating hemostatic valve (RHV) or Y-adapter.

The Direxion and Direxion HI-FLO Microcatheters are available with the following preloaded guidewires:

Fathom-16 Steerable Guidewire

- 0.016 in (0.41 mm) diameter; 140 or 180 cm lengths

Transend 14/18 Steerable Guidewires

- 0.014 in (0.37 mm) or 0.018 in (0.47 mm) diameters; 135, 165 or 190 cm lengths

The guidewires have a hydrophilic coating to provide lubricity, which aids in the navigation of distal, tortuous vasculature. The guidewires are radiopaque to allow for visualization under fluoroscopy and the tips are shapeable.

Accessories may include a RHV or Y-adapter, steam shaping mandrel, microcatheter introducer, guidewire introducer and torque device.

Intended Use / Indications for Use

The Direxion and Direxion HI-FLO Torqueable Microcatheters are intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

Comparison of Technological Characteristics

The Direxion and Direxion HI-FLO Torqueable Microcatheters are similar in fundamental design, function, materials, packaging, sterilization, operating principle, intended use / indication for use and fundamental technology as the predicate device. Modifications were made to the coating length, pre-shaped tips (Bern, J, Swan), and packaging of the Direxion Microcatheter.

Performance Data

The following testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. The Direxion Microcatheters met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.

- OD/ID Dimensional Requirements
- Guide Catheter Compatibility
- Microcatheter Surface Defects
- Microcatheter Coating Length
- Distal Joint Integrity
- RO Marker band Tensile
- Embolic Coil Compatibility
- Initial Tip Shape
- Packaging Mandrel Removal Force
- Sterile Barrier Integrity
- Device Containment in Packaging
- Microcatheter System Removal from Packaging

Conclusion

Boston Scientific has demonstrated that the modifications to the Direxion Microcatheters are substantially equivalent in fundamental design, technology, function, materials, packaging, operating principle, and intended use / indication for use as the predicate device.