510(k) Summary

Per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311 USA
Contact Name and Information	Maureen Sundeen Principal of Regulatory Affairs Phone: 763-494-2903 Fax: 763-494-2222 Email: sundeenm@bsci.com
Date Prepared	September 18, 2013
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 21 CFR 870.1210 Product Code: KRA Classification Panel: Cardiovascular
Predicate Device	Boston Scientific Renegade HI-FLO Microcatheter (K100892, KRA, April 12, 2010)

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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.

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 Neck, and J Shape) 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 (K111485)
- 0.016 in (0.41 mm) diameter; 140 or 180 cm lengths

Transend 14/18 Steerable Guidewires (K971254 / K964611)
- 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.

Comparison of Technological Characteristics

The Direxion and Direxion HI-FLO Torqueable Microcatheters are similar in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use / indication for use and fundamental technology as the predicate device, Renegade HI-FLO Microcatheter. The modifications from the predicate device include changes to catheter design and materials for added pushability, steerability, and torqueability in accessing the treatment site. In addition the microcatheters are provided with preloaded guidewires for physician convenience. A minor change was made to the packaging design to accommodate the preloaded guidewires.

Performance Data

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

- Microcatheter Luer Compatibility
- Microcatheter ID / OD Verification
- Catheter Usable Length
- Microcatheter Coating Integrity
- Particulate Evaluation
- Tensile Strength
- Corrosion Resistance
- Kink Resistance
- Distal Tip Flexibility
- Proximal Shaft Pushability
- Torsional Strength
- Maximum Infusion Pressure
- Freedom from Liquid Leakage
- Embolic Coil Compatibility
- PVA Particle and Embolic Sphere Compatibility
- Chemical Compatibility
- Guide Catheter Compatibility
- Guidewire Compatibility
- Torque Device Compatibility
- Y-Adapter / RHV Compatibility
- Shelf Life
- Packaging Testing
- Sterilization
- Biocompatibility

Conclusion

Boston Scientific has demonstrated that the modification made for the Direxion and Direxion HI-FLO Torqueable Microcatheters are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the predicate device, Renegade HI-FLO Microcatheter.

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

October 18, 2013

Boston Scientific Corporation
Ms. Maureen Sundeen
Principal of Regulatory Affairs
One Scimed Place
Maple Grove, MN 55311

Re: K132947
Trade/Device Name: Direxion™ Torqueable Microcatheter and Direxion™ HI-FLO™ Torqueable Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheters
Regulatory Class: II
Product Code: KRA
Dated: September 18, 2013
Received: September 19, 2013

Dear Ms. Sundeen:

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 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. 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,

Bram D. Zuckerman -S

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

Indications for Use

510(k) Number (if known): _____

Device Name:

Direxion™ Torqueable Microcatheter
Direxion™ HI-FLO™ Torqueable Microcatheter
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

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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Bram D. Zuckerman -S
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