K100892

Boston Scientific

Cardiovascular
One Scimed Place
Maple Grove, MN 55311-1566
763.494.1700 Tel
www.bostonscientific.com

510(k) Summary
per 21 CFR §807.92 (c)

APR 12 2010

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Scott Sepple Regulatory Affairs Specialist Tel: 763.494.2028 Fax: 763.494.2222 E-mail: Scott.Sepple@bsci.com
Date Prepared	March 30, 2010
Trade Name	Renegade™ Hi-Flo™ Fathom™ Kit
Common Name	Microcatheter kit
Classification Name	Catheter, continuous flush (21 CFR Part 870.1210, Product Code KRA)
Predicate Device	Boston Scientific Renegade Hi-Flo Microcatheter Kit — K000177 — SE: 7 April 2000
Device Description	The Renegade Hi-Flo Fathom Kit includes a Renegade Hi-Flo Microcatheter, a Fathom-16 Steerable Guidewire, a steam shaping mandrel, a rotating hemostatic valve (RHV), a guide wire torque device, and a guide wire introducer. The Renegade Hi-Flo Microcatheter lumen is able to accommodate steerable guidewires that are ≤ 0.018 in (0.46 mm) in diameter. The outer surface of the microcatheter distal segment is coated and has a radiopaque marker at the distal tip to facilitate fluoroscopic visualization. The distal tip of the microcatheter is steam shapeable using the

Device Description, continued	included steam shaping mandrel and the proximal end of the microcatheter incorporates a standard luer adapter to facilitate the attachment of the rotating hemostatic valve (RHV). The Fathom-16 Steerable Guidewire has a maximum diameter of 0.016 in (0.41 mm). The distal portion of the device is coated for lubricity and is radiopaque to facilitate fluoroscopic visualization. The torque device included with the guidewire attaches to the proximal end of the guidewire and functions as a steering mechanism. The guidewire introducer facilitates insertion of the guide wire into the microcatheter hub and/or hemostatic valve and may be used to shape the guidewire distal tip.
Indications for Use	The Renegade Hi-Flo Fathom Kit is intended for peripheral vascular use. The Fathom guidewire can be used to selectively introduce and position the Renegade Hi-Flo microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. Indications for use for the Renegade Hi-Flo Fathom Kit are a combination of the indications for use of the Renegade Hi-Flo Microcatheter and Fathom-16 Steerable Guidewire.
Comparison of Technological Characteristics	The Renegade Hi-Flo Fathom Kit technological characteristics are identical to the predicate Boston Scientific Renegade Hi-Flo Microcatheter Kit. The Renegade Hi-Flo Fathom Kit and predicate kit both contain a microcatheter, a guidewire, a microcatheter steam shaping mandrel, a rotating hemostatic valve (RHV), a guidewire torque device, and a guidewire introducer. The primary difference between the predicate and subject kit is the guidewire. The predicate kit includes the BSC Transend Guidewire and the Renegade Hi-Flo Fathom Kit includes the Fathom-16 Steerable Guidewire. The Fathom-16 Steerable Guidewire features a smaller outer diameter, a Nitinol distal tip, and longer lengths compared to the Transend-18 Guidewire included in the predicate kit.

Non-Clinical Performance Data

Determination of substantial equivalence is based on an assessment of non-clinical performance data. Non-clinical performance data submitted in support of substantial equivalence is based on the Failure Modes/Effects Analysis (FMEA) risk analysis method completed for the Renegade Hi-Flo Fathom Kit to assess the impact of the modifications to the predicate device.

Testing performed and summarized as a result of the completed FMEA and how this testing supports substantial equivalence is described below.

Test Data Submitted	How results support SE
Subject kit components compatibility	Results demonstrate impact of modification to replace Transend-18 Guidewire with Fathom-16 Steerable Guidewire
Packaging performance/ functional testing	Results demonstrate impact of modifications to predicate kit packaging
Performance testing of the kit guidewire post-sterilization	Results demonstrate impact to Fathom-16 Steerable Guidewire as a result of contract sterilizer and sterilization cycle for predicate kit
Sterilization qualification summary	Results demonstrate impact to Fathom-16 Steerable Guidewire as a result of contract sterilizer and sterilization cycle for predicate kit

All testing performed and data included in submission demonstrate passing results according to executed verification protocols. Therefore, results of non-clinical performance data submitted supports substantial equivalence to predicate device.

Clinical Performance Data

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

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Conclusion	Modification does not affect the intended use or alter the fundamental scientific technology of the predicate Boston Scientific Renegade Hi-Flo Microcatheter Kit. Based on the Indications for Use, unaltered technological characteristics, and submitted non-clinical performance data supporting this modification, the Boston Scientific Renegade Hi-Flo Fathom Kit is shown to be appropriate for its intended use and demonstrates that the device is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 12 2010

Boston Scientific Corporation
c/o Mr. Scott Sepple
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, Minnesota 55311

Re: K100892
Trade/Device Name: Renegade Hi-Flo Fathom Kit
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: March 30, 2010
Received: March 31, 2010

Dear Mr. Sepple:

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,

Bram D. 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): K100892

Device Name: Renegade™ Hi-Flo™ Fathom™ Kit

Indications for Use:

The Renegade™ Hi-Flo™ Fathom™ Kit is intended for peripheral vascular use. The Fathom guidewire can be used to selectively introduce and position the Renegade Hi-Flo microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels.

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 CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100892