MAR - 5 2010

K093968

Boston Scientific

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510(k) Summary

Date Prepared: December 22, 2009

Submitted by: Boston Scientific CRM
4211 Hamline Avenue North
St. Paul, Minnesota 55112-5798

Contact Person: Kathleen Vittum
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651-582-4820 (Telephone)
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Trade name: ACUITY Break-Away™ Delivery System
Common name: Percutaneous Catheter
Classification: Class II, 21 CFR 870.1250
DQY

Predicate devices: RAPIDO™ Cut-Away™ Guiding Catheter
(K031505)

Device Description: The ACUITY Break-Away™ Delivery System consists of two guide catheters plus the following accessories: torque device, guidewire introducer and cutter. The system is designed to provide venous access and to aid with the selective placement of implantable venous leads in the left cardiac vasculature. The catheters, provided in a 8F size and 6F size models, are packaged separately. The 8F catheter package also contains the torque device and guidewire introducer accessories, which assist with implanting the lead, and the cutter, which is used to facilitate removal of the catheters after implant. The 6F catheter is packaged alone. The 8F catheter may be used by itself or in conjunction with the 6F catheter in a telescoping manner to improve the access and delivery capabilities of the system.

The ACUITY Break-Away catheter models feature a hub that is manually split apart rather than cut, and also incorporate a hemostasis valve to eliminate the need for an external accessory valve. The catheter is designed with a flexible distal segment and a soft tip to atraumatically enter the main coronary sinus and branch veins. The 6F ACUITY Break-Away catheter must be used with an 8F ACUITY Break-Away guide catheter to gain access to the main coronary sinus

ACUITY Break-Away 8F Guide Catheters are available in the following shapes:

- Extended Hook (CS-EH)
- Right (CS-EH ST R)
- Wide (CS-W)
- Multipurpose (CS-MP)
- Coronary Sinus Hook (CS-H)
- Amplatz (CS-A6)
- Straight (CS-ST)

ACUITY Break-Away 6 Fr. Inner Catheter are available in the following shapes:

- 90 degree (CS-IC 90)
- 130 degree (CS-IC 130)

Complete US Model List:

- 7063 6F 68CM 90 DEG (Degree)

- 7064 6F 63CM 90 DEG
- 7065 6F 68CM 130 DEG
- 7066 6F 63CM 130 DEG
- 7067 8F 54CM EH (Extended Hook)
- 7068 8F 49CM EH
- 7069 8F 54CM EH ST R (Extended Hook Straight Right)
- 7070 8F 49CM EH ST R
- 7071 8F 54CM W (Wide)
- 7072 8F 49CM W
- 7073 8F 54CM MP (Multipurpose)
- 7074 8F 49CM MP
- 7075 8F 54CM H (Hook)
- 7076 8F 49CM H
- 7077 8F 54CM AMP (Amplatz
- 7078 8F 49CM AMP
- 7079 8F 54CM ST (Straight)
- 7080 8F 49CM ST

Intended Use: The ACUITY Break-Away™ Delivery System is intended to access the coronary venous system and may be used alone (8F) or in dual catheter delivery (8F with 6F).. The catheters serve as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

Technological Characteristics:

- **Similarities:** The ACUITY Break-Away Catheters and predicate RAPIDO Cut-Away Catheters share these characteristics:
  - Same fundamental design - serving as a single or dual-catheter delivery conduit for leads or contrast medium.
  - Catheter bodies are constructed from the same basic materials.
  - Require use of a cutting accessory to separate the outer catheter for removal.
- **Differences:** The Acuity Break-Away Catheters differ from the predicate RAPIDO Cut-Away catheters in the following respects:
  - Design and material change in the hub from plastic to a breakable resin material, which allows hub to be split manually rather than cut. (The catheter body must still be cut.)
  - The predicate catheter requires use of a separate hemostasis accessory (a rotating hemostasis valve or bleedback control valve) during lead implant. The new catheters have a built-in hemostasis valve and do not require a separate accessory.
  - Tungsten has been added to the Break-Away catheter tip to increase radiopacity

Summary of Non-Clinical Testing: Design verification testing, including mechanical bench testing, animal testing and heart modeling, were conducted to verify that the performance of ACUITY Break-Away catheters remains substantially equivalent to the predicate devices. Biocompatibility, packaging and sterility testing were also performed.

Test results confirm that the modified catheters continue to meet all design and performance specifications. Biocompatibility testing confirmed that the modified catheters continue to conform with ISO standard 10993-1 (Biological Evaluation of Medical Devices – Evaluation and Testing), and can be effectively sterilized in accordance with sterilization standard ISO 11137.and EtO residual standard ISO 11135

Summary of Clinical Testing: Clinical evaluation was not required.

Statement of Substantial Equivalence: Results of testing and evaluation demonstrate that the ACUITY Break-Away Catheters are similar to the RAPIDO Cut-Away Catheters in the following aspects:.

* Same intended use,

* Same operating principle

* Same basic design,

* Catheter body contains the same primary materials

Therefore, Boston Scientific considers ACUITY Break-Away Delivery System to be substantially equivalent to the legally marketed predicate devices.

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

MAR - 5 2010

Boston Scientific Corporation
c/o Ms. Kathleen Vittum
4100 Hamline Avenue North
St. Paul ,MN 55112

Re: K093969
Trade/Device Name: ACUITY Break-Away™ Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: February 3, 2010
Received: February 4, 2010

Dear Ms. Vittum:

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.

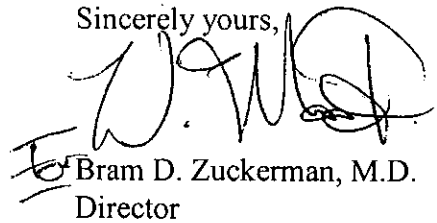
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

INDICATION FOR USE STATEMENT

510(k) Number (if known): K093969

Device Name: **ACUITY Break-Away™ Lead Delivery System**

Indications For Use:

The ACUITY Break-Away™ Lead Delivery System is intended to access the coronary venous system and may be used alone (8F) or in dual catheter delivery (8F with 6F). The system serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

Prescription Use: [X] AND/OR Over-The-Counter Use: [ ]

(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K093969