



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 20, 2015

Abbott Vascular
Ms. Aruna Akkapeddi
Senior Regulatory Affairs Specialist
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K153086

Trade/Device Name: RX ACCUNET Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: October 29, 2015
Received: October 30, 2015

Dear Ms. Akkapeddi:

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 yours,

Kenneth J. Cavanaugh -S

for

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)

K153086

Device Name

RX ACCUNET EMBOLIC PROTECTION SYSTEM

Indications for Use (Describe)

The RX ACCUNET Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus / debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.25 mm and 7.0 mm.

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.

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510(k) Summary

The 510(k) Summary is submitted in accordance with 21 CFR §807.92 and the requirements of the Safe Medical Device Act (SMDA) of 1990.

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| 1. <u>Submitter's Name</u> | Abbott Vascular |
| 2. <u>Submitter's Address</u> | 3200 Lakeside Drive, Santa Clara, CA 95054 |
| 3. <u>Telephone</u> | 408-845-1648 |
| 4. <u>Fax</u> | (408) 845-3743 |
| 5. <u>Contact Person</u> | Aruna Akkapeddi |
| 6. <u>Date Prepared</u> | November 18, 2015 |
| 7. <u>Device Trade Name</u> | RX ACCUNET Embolic Protection System |
| 8. <u>Device Common Name</u> | Embolic Protection System |
| 9. <u>Device Classification Name</u> | 21 CFR 870.1250, Percutaneous Catheter |
| 10. <u>Predicate Device Name</u> | RX ACCUNET Embolic Protection System (K052166, cleared August 18, 2005), and RX ACCUNET Embolic Protection System (K042218, cleared August 31, 2004). |

11. Device Description

The RX ACCUNET Embolic Protection System is a filtration type embolic protection device, filtering distal to the interventional site. The System consists of the RX ACCUNET™ Delivery System, the RX ACCUNET Recovery Catheter, Shapeable Tip Design and the RX ACCUNET 2 Recovery Catheter, Low-Profile, Flexible Tip Design all packaged together in one chipboard carton. The RX ACCUNET Embolic Protection System is delivered via a Delivery Sheath with a flexible tip coil that facilitates movement of the Sheath through tortuous anatomy. Once across the lesion, the Filter Basket is expanded in the arterial lumen by peeling the Delivery Sheath from the guide wire using the torque device and peel away adapter. At the conclusion of the interventional procedure, the Filter Basket is collapsed inside one of the provided Recovery Catheters. Recovery Catheter selection is based on physician preference and/or patient anatomy. Once collapsed, the entire system is removed as a single unit. The Recovery Catheters have radiopaque tips to facilitate movement through tortuous anatomy. The change being made is to the formulation of an adhesive that is used to adhere two core subassemblies.

12. Indication for Use

The RX ACCUNET Embolic Protection System is indicated for use as a guide wire and embolic protection system to contain and remove embolic material (thrombus / debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.25 mm and 7.0 mm.

13. Technological Characteristics

Reformulation of Loctite 648 adhesive that is used to adhere the proximal core to the distal core by using a hypotube is being made as a product improvement. Comparisons of the new and predicate devices show that the technological characteristics such as product performance, materials, design, sterilization, packaging, and intended use are substantially equivalent to the current marketed predicate devices.

14. Performance Data

In vitro bench testing performance evaluations was successfully conducted on the RX ACCUNET Embolic Protection System. *In vitro* functional bench testing conducted on the subject device included:

- Hypotube adhesion pull test

The testing demonstrated that the RX ACCUNET Embolic Protection System met the acceptance criteria and performed comparable to the predicate devices. No new safety or effectiveness issues were raised during the testing and therefore, the RX ACCUNET Embolic Protection System may be considered substantially equivalent to the predicate devices.

Biocompatibility testing included cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogen, hemolysis, coagulation and complement activation. Biocompatibility testing was conducted in accordance with ISO 10993-1 and the results confirm that the device with the modified adhesive formulation remains appropriate for its intended use.

Conclusions

Test results from the non-clinical *in vitro* bench testing conducted on the RX ACCUNET Embolic Protection System met all acceptance criteria and show that it performed similarly to the predicate devices. There were no new safety or effectiveness issues raised during the testing program.

The RX ACCUNET Embolic Protection System is substantially equivalent to the predicate device in regards to the indications for use, materials, fundamental technology, design, performance, biocompatibility, sterilization, and packaging.