510(k) SUMMARY

AUG 19 2008

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92

Submitter's Name:	Abbott Vascular Inc.
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95052
Telephone: **Fax**:	408-845-0633 408-845-0921
Contact Person:	Virginia Singer Regulatory Affairs Advisor
Date Prepared:	May 7, 2008
Device Trade Name:	RX ACCUNET® LP Embolic Protection System
Device Common Name:	Embolic Protection System
Device Classification Name:	Embolic Protection System
Device Classification:	Class II, NTE

Summary of Substantial Equivalence:

The proposed RX ACCUNET® LP Embolic Protection Systemis substantially equivalent to the currently marketed RX ACCUNET® Embolic Protection System cleared in K052166 and K052165, respectively, on August 18, 2005.

Device Description:

The RX ACCUNET® LP Embolic Protection System is a low profile filtration type embolic protection device, filtering distal to the interventional site. The System consists of the RX ACCUNET® LP 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® LP Guide Wire with Filter Basket 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 will be 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 though tortuous anatomy.

Indication for Use:

The RX ACCUNET® LP 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.

Technological Characteristics:

The RX ACCUNET® LP Embolic Protection System is substantially equivalent to the RX ACCUNET® Embolic Protection Systems (K052166 and K052165) with regard to device design, principles of operation, materials, and indications for use. The following design attributes are the same or similar for both the subject device and the predicate devices:

- Rapid exchange systems
- Filter based technology
- Polyurethane filter membrane
- Nitinol filter/basket component
- Compatibility with .014" guidewires
- Compatibility with 6F guide sheaths and 8F guide catheters
- Accommodates same vessel sizes
- Radiopaque guidewire tips and/or delivery sheath tips
- Radiopaque markers on filter
- Delivery System /Recovery Catheter compatability

Comparisons of the subject and predicate devices show that technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging are substantially equivalent to the currently marketed predicate devices.

Performance Data:

The results of the bench, *in vitro*, *in vivo*, sterilization qualification and packaging validation studies have demonstrated the substantial equivalence of the proposed RX ACCUNET® LP Embolic Protection System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2008

Abbott Vascular Inc.
c/o Ms. Danielle Taylor
Regulatory Affairs Manager
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K081549
Trade/Device Name: RX Accunet® LP Embolic Protection System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: August 6, 2008
Received: August 7, 2008

Dear Ms. Taylor:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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): ____Not known K081549

Device Name: __RX Accunet® LP Embolic Protection System

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081549