

MAR 26 2008

**510(k) Summary****Summary Information**

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

Submitter's Name: Abbott Vascular

Submitter's Address: 3200 Lakeside Drive  
Santa Clara, CA 95054

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Contact Person: Ivalee Cohen  
Manager, Regulatory Affairs

Date Prepared: January 31, 2008

Device Trade Name: Fox™ Plus PTA Catheter

Device Common Name: PTA Catheter

Device Classification: Class II

Device Classification Number: 21 CFR 870.1250

Device Product Code: LIT

**Predicate Devices**

The subject device is substantially equivalent to the Fox Plus PTA Catheter predicate device (K040954, cleared on May 11, 2004) and to the Sailor™ Plus PTA Balloon Dilatation Catheter predicate device (K042538, cleared on November 8, 2004).

**Device Description**

The Fox Plus PTA Catheter is a standard over-the-wire PTA catheter. The double lumen catheter has a balloon located near the distal tip. One lumen is used for inflation of the balloon, while the second lumen allows access to the distal tip of the catheter for guidewire insertion (max 0.035"). The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The balloon material expands to a known diameter at specific pressures.

**Intended Use**

The intended use for the device has not changed as a result of the modification.

The Fox Plus PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae. This catheter is not intended for the expansion or delivery of stents.

#### **Summary of Technological Characteristics Compared to Predicate Devices**

The Fox™ Plus PTA Catheter subject device is identical in technological characteristics, with the exception of balloon lengths, to the Fox Plus PTA Catheter predicate device. The subject device is also substantially equivalent to the Sailor™ Plus PTA Balloon Dilatation Catheter with respect to product code, classification section, classification name, intended use, catheter length, balloon diameters and lengths, introducer sheath size, and guidewire compatibility.

#### **Summary of Substantial Equivalence**

The Fox Plus PTA Catheter subject device is substantially equivalent to the predicate devices. The results of the *in vitro* bench tests and analyses and biocompatibility testing demonstrate the safety and effectiveness of the Fox Plus PTA Catheter subject device.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAR 26 2008**

Abbott Vascular  
c/o Ms. Ivalee Cohen  
3200 Lakeside Drive  
Santa Clara, CA 95054

Re: K080264

Trade Name: Fox<sup>TM</sup> Plus PTA Catheter

Regulation Number: 21 CFR 870.1250

Regulation Name: Percutaneous Transluminal Angioplasty Catheter

Regulatory Class: Class II (two)

Product Code: LIT

Dated: January 31, 2008

Received: February 1, 2008

Dear Ms. Cohen:

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 Biometric's (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 Statement**

510(k) Number (if known): K080264

Device Name: Fox™ Plus PTA Catheter

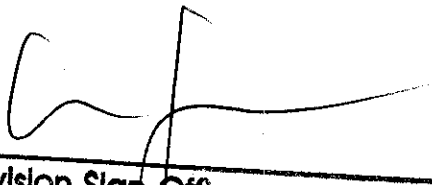
**Indications for Use:**

The Fox Plus PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal and profunda arteries and native or synthetic arteriovenous dialysis fistulae.

This catheter is not intended for the expansion or delivery of stents.

Prescription Use X OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K080264