510(k) Summary

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
FDA Registration Number:	3004635528
Telephone: Fax:	408-845-0869 408-845-0921
Contact Person:	Cherece L. Jones, Regulatory Affairs Associate
Date Prepared:	September 24, 2007
Device Trade Name:	Viatrac® 14 PLUS Peripheral Dilatation Catheter
Device Common Name:	Catheter, Percutaneous
Product Code :	DQY
Device Classification:	Class II

JAN 31 2008

Summary of Substantial Equivalence:

The Viatrac 14 PLUS Peripheral Dilatation Catheter with modified indications is substantially equivalent to the Viatrac 14 PLUS Peripheral Dilatation Catheter (K012050, cleared 09/06/2001) in addition to the currently marketed predicate devices, the Sterling Monorail PTA Balloon Dilatation Catheter, K053118 and the Cordis Aviator PLUS Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter, K071189. Changes made to the Viatrac 14 PLUS Peripheral Dilatation Catheter will more closely align the indications with Clinical use. There are no changes to the device included in this proposal or as a result of this change.

Device Description:

The Viatrac 14 PLUS Peripheral Dilatation Catheter has an integrated shaft system and a balloon near the distal tip. The shaft has a combination of single lumen and dual lumen tubing. One lumen is used for inflation of the balloon with contrast medium. The second lumen in the distal shaft permits the use of a guide wire to facilitate the advancement of the catheter to and through the stenosis to be dilated.

The balloon has radiopaque marker(s) to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure.

On the 135 cm catheter length, there are two proximal shaft markers (95 cm and 105 cm from the distal tip). On the 80 cm catheter length, there is a single proximal marker (55 cm from the distal tip). Both indicate the relative position of the catheter to the end of a brachial, femoral or renal guiding catheter. An additional marker is located at the guide wire exit notch and aids in locating the guide wire exit notch.

The design of this catheter does not incorporate a lumen for distal dye injections and distal pressure measurements.

Intended Use:

The Viatrac 14 PLUS Peripheral Dilatation Catheter is indicated to dilate stenosis in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal and carotid arteries) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Technological Characteristics:

There have been no changes to the technological characteristics such as materials, biocompatibility, performance properties, sterilization and packaging therefore they are substantially equivalent to the currently marketed predicate devices.

Performance Data:

The substantial equivalence of the Viatrac 14 PLUS Peripheral Dilatation Catheter has been demonstrated through data collected from in vitro bench tests and retrospective analyses of clinical studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

Abbott Vascular, Inc.
c/o Ms. Cherece Jones
Regulatory Affairs Associate
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K072798
Trade/Device Name: Viatrac 14 PLUS Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: September 24, 2007
Received: October 1, 2007

Dear Ms. Jones:

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,

Donna R. Bachner

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) K072798

Device Name Viatrac® 14 PLUS Peripheral Dilatation Catheter

Indications for Use

The Viatrac® 14 PLUS Peripheral Dilatation Catheter is indicated to dilate stenosis in the peripheral vasculature (iliac, femoral, ilio-femoral, popliteal, infra-popliteal, renal arteries, and carotid arties) and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon-expandable and self-expanding stents in the peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use ____ (Part 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)

Donna R. Vachney

(Division Sign-Off)

Cardiovascular Devices

Number K072798