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510(k) Summary - Admiral™.035 Dilatation Catheter

Submitter	Avantec Vascular Corporation 1049 Kiel Court Sunnyvale, CA 04089
Date Prepared	January 6, 2003
Contact Person	James M. Shy Phone: (408) 743-3125 FAX: (408) 548-0088 e-mail: jshy@avantecvascular.com
Device Trade Name	Admiral™.035 Dilatation Catheter
Device Common Name	Peripheral Transluminal Angioplasty (PTA) Catheter
Classification Name	21 CFR 870.1250 Percutaneous Catheter
Device Classification	Regulatory Class: Class II (two) Product Code: 74 LIT
Predicate Device	Boston Scientific Medi-Tech® MARSHAL™ Balloon Dilatation Catheter
Performance Standards	Not promulgated for PTA Catheters.
Intended Use	The Admiral™ .035 Dilatation Catheter is indicated for percutaneous transluminal angioplasty of the femoral, renal, iliac, popliteal, peroneal and profunda arteries and native or synthetic arteriovenous dialysis fistulae. It is not intended for use in the coronary vasculature or the neurovasculature.
Device Description	The Admiral™ .035 Dilatation Catheter is an Over-the-Wire, Coaxial, dual lumen design with a inflatable balloon on the distal end and compatible with 0.035" guidewires. Two radiopaque markers indicate the dilating portion of the balloon and aid in balloon placement. The device is available with balloon diameters of 7.0 – 10.0 mm, balloon lengths of 20, 30 & 40 mm and catheter lengths of 80 & 135 cm.
Biocompatibility	The Admiral™ .035 Dilatation Catheter has passed all Biocompatibility testing.
Performance Data	Performance testing was conducted to demonstrate Safety and Effectiveness and for comparison to the predicate device. Testing included: Balloon Minimum Burst Strength, Compliance, Fatigue, and Inflation/Deflation performance, Bond Strengths and Coating Integrity.
Summary	The Admiral™ .035 Dilatation Catheter is constructed of similar materials, is available in similar diameters and lengths, has a similar design and the same indications as the Predicate Device and other currently marketed PTA Catheters. Bench and Biocompatibility testing has demonstrated the safety and effectiveness of the device.
Conclusion	The Admiral™ .035 Dilatation Catheter is substantially equivalent to the predicate device and other currently marketed PTA Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 2003

Avantec Vascular Corporation
c/o Mr. James M. Shy
1049 Kiel Court
Sunnyvale, CA 04089

Re: K030062
Trade Name: Admiral™ .035 Dilatation Catheter
Regulation Number: 21 CFR §870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: January 6, 2003
Received: January 7, 2003

Dear Mr. Shy:

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 Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030062

Device Name: Admiral™ .035 Dilatation Catheter

Indications for Use:

The Admiral™ .035 Dilatation Catheter is indicated for percutaneous transluminal angioplasty of the femoral, renal, iliac, popliteal, peroneal and profunda arteries and native or synthetic arteriovenous dialysis fistulae. It is not intended for use in the coronary vasculature or the neurovasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The- Counter _____
(Per 21 CFR 801.109)

(Optional Format 1-1-96)

(Division Sign-Off)
Division of Cardiovascular
510(k) Number K030062