K965183

APR 24 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510 (k) summary of safety and effectiveness information is being submitted in accordance with the requirement of SMDA 1990.

1. Submitted by

Advanced Cardiovascular Systems
3200 Lakeside Drive
Santa Clara, CA 95052

2. General Information

Device Name: VANTAGE™ Peripheral Dilatation Catheter- Additional Sizes

Predicate Device: VANTAGE™ Dilatation Catheter (ACS)
Ultra-thin™ Dilatation Catheter (Medi-Tech)

Common Name: PTA Balloon Dilatation Catheter

Device Classification: Class II

3. Indications for Use

The VANTAGE™ Peripheral Dilatation Catheter is intended for use in Percutaneous Transluminal Angioplasty (PTA) of the Iliac, Femoral, and Popliteal arteries. The VANTAGE™ Peripheral Dilatation Catheter is not intended for use in the coronary arteries or in neurovasculature.

4. Product Description

The 10 cm VANTAGE™ Peripheral Dilatation Catheter is a double-lumen catheter with a poly(ethylene)terephthalate (PET) balloon bonded to the shaft. The 10 cm VANTAGE™ Peripheral Dilatation Catheter has a range of balloon sizes from 3 mm to 7 mm in inflated diameter. The catheter is available in 75 cm to 125 cm shaft lengths.

5. Rationale for Substantial Equivalence

The 10 cm VANTAGE™ Peripheral Dilatation Catheter is substantially equivalent to the ACS VANTAGE™ Dilatation Catheter (510 (k) Notification K934433) and Medi-Tech's Ultra-thin™ Balloon Dilatation Catheter (510 (k) Notification K920547). The 10 cm VANTAGE™ Peripheral Dilatation Catheter is equivalent

to the VANTAGE™ and Ultra-thin™ Balloon Dilatation Catheters in term of its indications for use, functionality, performance and safety. The VANTAGE™ Dilatation Catheter and Ultra-thin™ Balloon Dilatation Catheter were found to be substantially equivalent to devices which were in commercial distribution prior to May 28, 1976.

6. Safety and Performance Studies

The following tests were performed on the 10 cm VANTAGE™ Peripheral Dilatation Catheter:

1) Catheter Preparation Test
2) Balloon Minimum Burst Strength Test (Balloon Rupture)
3) Balloon Compliance Test (Distensibility)
4) Balloon Inflation/Deflation Tests
5) Balloon Fatigue Test (Repeated Balloon Inflation)
6) Tip Pulling Test
7) Bonding Strength Test
8) Catheter Body Burst Pressure Test
9) Contrast Medium Flow Rate Test
10) Dimensional Measurements (Tip Diameter and Profile Test)

The results of each of the tests were found to be clinically acceptable.

The 10 cm VANTAGE™ Peripheral Dilatation Catheter has been tested per the Tripartite Biocompatibility Guidelines and has passed the USP Class IV for plastics. The following biocompatibility tests were conducted:

1) Cytotoxicity - Elution
2) Sensitization
3) USP XXII Plastics Test (Class IV) - Intracutaneous Test

The 10 cm VANTAGE™ Peripheral Dilatation Catheter passed each of the biocompatibility tests conducted.

7) Conclusions

Based upon the indications for use, technological characteristics, and safety and performance studies, the 10 cm VANTAGE™ Peripheral Dilatation Catheter has been shown to be safe and effective for its intended use.