SECTION 2 - 510(k) SUMMARY

K963688
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Submitted By:

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Summary Preparation:

September 13, 1996

Device:

FOCUS™-PV Balloon Dilatation Catheter

Classification Name:

Catheter, Peripheral, Balloon Type

Predicate Device:
PTA Catheters:

Match 35™ PTA Balloon Catheters
Schneider

Total Cross™ Balloon Dilatation Catheter
Schneider

MS Classique™ Balloon Dilatation Catheter
Medi-tech

Ultra-Thin™ Balloon Dilatation Catheter
Medi-tech

FOCUS™ Balloon Dilatation Catheter
CardioVascular Dynamics, Inc.
510(k) K944016
SE Date: December 20,1994

FOCUS™ Balloon Dilatation Catheter
CardioVascular Dynamics, Inc.
510(k) K952064
SE Date: June 21, 1995

FOCUS™ Balloon Dilatation Catheter
CardioVascular Dynamics, Inc.
510(k) K954313
SE Date: December 1, 1995

The FOCUS™-PV Balloon Dilatation Catheter is a balloon dilatation catheter intended for use in percutaneous transluminal balloon dilatation (PTA) of large vessels of the peripheral vasculature.

The FOCUS™-PV Balloon Dilatation Catheter, styled after the Grüntzig technique, is a double lumen catheter with a balloon mounted at the distal tip. Dilatation Balloon catheters are used to exert radial force to dilate narrow vessel segments, based on the principle of hydraulic pressurization applied through an inflatable balloon attached to the distal end of a catheter.

There are many commercially available catheters indicated for peripheral transluminal balloon angioplasty which were marketed prior to promulgation of the Act (May 28, 1976) or have been found substantially equivalent to pre-enactment devices. The FOCUS™-PV device is intended for use in exactly the same manner. In particular, the FOCUS™-PV Balloon Dilatation Catheter is equivalent in indications and intended use to the listed predicate devices in the table below.

All catheters are manufactured from similar biocompatible materials. They are all preformed plastic tubes with luer fittings.

The FOCUS™-PV Balloon Dilatation Catheter is a peripheral balloon dilatation catheter. The FOCUS™-PV Balloon Dilatation Catheter is substantially equivalent to existing balloon dilation catheters.

The FOCUS™-PV Balloon Dilatation Catheter is designed for use during peripheral vascular balloon dilatation. Numerous catheters are available in a large range of sizes for use in this manner. The comparison table lists several commercially available devices. Comparisons are made based on the size, construction, materials and use.

This 510(k) is for modifications to existing devices, 510(k) number K944016, substantial equivalence December 20, 1994, 510(k) number K952064, substantial equivalence June 21, 1995, 510(k) number K954313, substantial equivalence December 1, 1995. Modifications include larger balloon sizes and reduced balloon compliance. The balloon changes from a double layer polyethylene with polyethylene terephalate to a single layer polyethylene terephalate balloon. The balloon is bonded with an adhesive to a nylon shaft instead of heat sealed to a polyethylene shaft. The catheter shaft tubing changes from a side by side tubing configuration to a coaxial tubing configuration.

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COMPARISON OF FOCUS™-PV WITH CURRENTLY MARKETED PTA CATHETERS

MANUFACTURER	CardioVascular Dynamics	CardioVascular Dynamics	Schneider	Schneider	Medi-tech	Medi-tech
Product Name	FOCUS Balloon Dilatation Catheter	FOCUS™-PV Balloon Dilatation Catheter	Match 35 PTA Balloon Dilatation Catheter	Total Cross PTA Balloon Dilatation Catheter	MS Classique Balloon Dilatation Catheter	MS Ultra-Thin Balloon Dilatation Catheter
Balloon Size	2.5 - 4.0 mm (0.5 incr.)	4.0/5.0-7.0/8.0 mm (1.0 incr)	3.0 - 10.0 mm	2.0 - 8.0 mm	4.0 - 10.0 mm	4.0 - 10.0 mm
Balloon Length	20, 25 mm	25, 30, 40 mm	20, 40, 80, 100 mm	20, 40, 80 mm	25, 40, 80, 100 mm	20, 40, 80, 100 mm
Shaft Size	3.5 F proximal 3.0 F distal	4.3F/5.0F	4.3F/5.0 F	4.3F	4.8F and 5.2F	5.0F
Shaft Length	135 cm	75 - 150 cm	75 - 150 cm	95 - 150 cm	75 - 120 cm	75 - 150 cm
Materials						
Balloon	Polyethylene/ PET	Polyethylene Terephalate (PET)	Polyethylene Terephalate (PET)	Polyethylene/ PET	Polyethylene Terephalate (PET)	Polyethylene Terephalate (PET)
Shaft	Polyethylene	Nylon	Polyester	Polyester	Polyester	Polyester
Guidewire Size (Max)	0.014 in.	0.018/0.035 in.	0.035 in.	0.021 in.	0.035 in.	0.035 in.

Testing of the FOCUS™-PV Balloon Dilatation Catheter included balloon burst, balloon cycle, radiopacity, tensile strength of connector to catheter shaft, catheter distal end tensile strength, profile measurements, and biocompatibility. These tests demonstrated the balloons meet or exceed specification as well as catheter tip profiles were within specification tolerances. Tensile strength of the catheter shaft and catheter tip as well as torsion strength of the catheter tip met design specifications. There were no failures during these tests.

Overall, all testing demonstrated that the FOCUS™-PV Balloon Dilatation Catheter is safe and effective.

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