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K963663

SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 13 1997

SUBMITTER: InterVentional Technologies, Inc. (IVT)
DATE: September 12, 1996
COMMON NAME: Guiding Catheter
PROPRIETARY NAME: 11F Guiding Catheter
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CLASSIFICATION: Class II per 21 CFR 870.1200, Diagnostic Intravascular Catheter (and 21 CFR 870.1250, Percutaneous Catheter)

PREDICATED DEVICES:

IVT is claiming substantial equivalence to the following predicate medical devices:

1. InterVentional Technologies, Inc., 5 - 10F Guiding Catheter, K911869
2. Devices for Vascular Intervention, Inc. (DVI), 11F Guiding Catheter
3. Cordis Webster, Inc., Multipurpose Guiding Catheter
4. Medtronic Interventional Medical, Guiding Catheter K822243

1. DEVICE DESCRIPTION:

The IVT 11F Guiding Catheter is a series of standard cardiovascular guiding catheters with models corresponding to standard catheter curvature types.

The IVT 11F Guiding Catheter contains a single lumen which acts as a conduit to provide access for other medical devices to the coronary vasculature. The device's proximal end contains a polycarbonate female luer fitting which can be connected to other equipment used in cardiovascular procedures. The 11F Guiding Catheter device is offered in a catheter working

length of 94 cm. The shaft is designed with a braided wire reinforcement and can include side holes to enable vessel perfusion during placement. The 11F Guiding Catheter's distal end is shaped to accommodate various anatomic configurations. The 11F Guiding Catheter curvatures include the FL 3.5, FL 4.0, FL 5.0, FR 3.5, FR 4.0, FR 5.0, Multi-purpose Graft, Modified Amplatz, Left Amplatz, Right Coronary Bypass, and Hockey Stick standard catheter shape types. The distal tip of the device is a "soft" tip design.

All IVT 11F Guiding Catheter device packaging configurations are supplied as sterile devices and intended for single use only.

2. INTENDED USE, INDICATIONS FOR USE:

The IVT 11F Guiding Catheter is a standard guiding catheter intended for use in the coronary vasculature as a conduit for other medical devices such as diagnostic and therapeutic catheters and guidewires. Thus, the IVT 11F Guiding Catheter acts to facilitate access for these other medical devices. This device is intended for single use only.

IVT's 11F Guiding Catheter is indicated for use during interventional diagnostic cardiovascular procedures in hospital settings which are appropriate for these types of procedures.

3. SUBSTANTIAL EQUIVALENCE:

The intended use of IVT's 11F Guiding Catheter is the same as that for other predicate guiding catheter devices. The materials and design of this device are similar to those of other, previously FDA cleared guiding catheters. The technical characteristics of 11F Guiding Catheter do not introduce new questions regarding safety or effectiveness of cardiovascular guiding catheters. The labeling associated with the 11F Guiding Catheter provides similar information as the predicate devices.

Biocompatibility and physical performance testing demonstrate IVT's 11F Guiding Catheter product to be safe and effective. Information provided in the 510(k) submission supports the determination of substantial equivalence.

In summary IVT has provided evidence that shows the 11F Guiding Catheter to be safe and effective. This device is considered to be substantially equivalent to similar marketed devices.