

K955886

Summary of Substantial Equivalence

Section 513(i) of the Federal, Drug and Cosmetic Act

December 1995

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I. General Provisions

Classification Name

None established

Common/Usual Name

Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Proprietary Name

Cordis Mega PTA Balloon Catheter

II. Name and Address of Applicant

Cordis Corporation
P.O. Box 025700
Miami, FL 33102-5700

Contact Name:

Martine D. Schneider
Martine D. Schneider, Regulatory and Clinical Affairs

III. Name of Predicate Devices

Cordis Savvy PTA Balloon Catheter
Cordis Opta 5 PTA Balloon Catheter
Cordis Small Vessel PTA Balloon Catheter
Schneider SofTrac

IV. Classification

PTA Balloon Catheters are classified as class II devices.

V. Performance Standards

Performance standards for PTA Balloon Catheters have not been established under Section 514 of the Food, Drug and Cosmetic Act.

VI. Intended Use and Product Description

The Cordis Mega PTA Balloon Catheters are designed for dilatation of stenotic lesions within the peripheral vessels. Mega catheters have a coaxial design (tube within a tube) with a balloon on the distal tip. Two (2) lumens, an inner and outer lumen, are split on the proximal end by a Y-shaped one piece hub. The inner lumen (denoted by "thru" molded into the hub) is used for contrast medium or saline injections and guidewire insertion (maximum guidewire diameter is 0.018"). The outer lumen (denoted by "balloon" molded into the hub) is used for inflation and deflation of the balloon. Two (2) radiopaque marker bands placed within the balloon working length aid the physician in proper balloon placement.

VII. Biocompatibility

All appropriate biocompatibility tests were performed and successfully passed on the materials used in the Mega PTA Balloon Catheter, as specified in the Tripartite Guidance Document.

VIII. Summary of Substantial Equivalence

The Cordis Mega Percutaneous Transluminal Angioplasty (PTA) Balloon catheters are designed for dilatation of stenotic lesions within peripheral vessels. Mega catheters have the same intended use and several of the same materials, design characteristics and dimensions as other currently marketed devices and the previously concurred Savvy catheters. Physical testing of the Mega PTA Balloon Catheters demonstrates equivalent performance to previously and existing PTA catheter designs.