07-00032

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Section 513(j) of the Federal Food, Drug and Cosmetic Act
Summary of Safety and Effectiveness

July 26, 1996

FEB 20 1997

I. General Provisions

Common or Usual name: PTA Balloon Catheter

Proprietary name: Cordis Maxi PTA Balloon Catheter

Name and Address of Applicant:
Cordis Corporation
Miami Lakes Operation Center
14201 NW 60 Avenue
Miami Lakes, FL 33014

II. Name of Predicate Devices

Cordis Opta 5 PTA Balloon Catheter
Cordis Powerflex 5F PTA Balloon Catheter
Cook Omega N.V. Balloon Dilatation Catheter

III. Classification

PTA catheters are class II devices according to 21 CFR 870.1340.

IV. Performance Standards

Performance standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

V. Intended Use and Device Description

The Maxi PTA catheter is intended to dilate lesions in large vessels. The device is an over-the-wire balloon catheter, with a distal balloon and a proximal hub. The balloon is indicated by two radiopaque marker bands.

VI. Biocompatibility

All appropriate biocompatibility testing was performed, and successfully passed, on the materials used for the Maxi PTA Catheter.

VII. In vitro Testing

A series of in vitro tests were performed to assure that the introduction of the Maxi PTA catheters does not raise new issues of safety and effectiveness. All test results met or exceeded established specifications.

VIII. Summary of Substantial Equivalence

The Maxi PTA catheter is designed for dilatation of stenotic lesions in large vessels. The Maxi PTA catheters have the same intended use, and several of the same materials, design characteristics and dimensions as the predicate devices.