APR 24 1997

PREMARKET NOTIFICATION 510(k)
Cordis Corporation
Jupiter PTA Catheters
January 24, 1997

K970299

Attachment 1
SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions:

Common Name: Percutaneous Transluminal Angioplasty Catheters

Proprietary Name: Jupiter PTA Catheters

II. Name of Predicate Devices:

a. Trade Name: Jupiter PTA Catheters
Manufacturer: Cordis Corporation

b. Trade Name: Opta 5 PTA Catheters
Manufacturer: Cordis Corporation

c. Trade Name: Ultra Thin PTA Balloon Catheter
Manufacturer: Medi Tech[1]

III. Classification:

Class II

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:

Jupiter PTA Catheters are designed for dilating stenotic atherosclerotic lesions in peripheral arteries (renal, popliteal, infra popliteal, femoral, and ilio femoral) and are also intended to treat obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

[1] A statement of substantial equivalence to another product is required by 21 CFR 807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA has stated".. A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits" 42 Fed. Reg. 42, 520 et seq. (1977).

VI. Biocompatibility

Since no new materials are being introduced in this submission, no additional biocompatibility testing was performed. All appropriate biocompatibility tests were successfully performed on Cordis Corporation's Jupiter PTA Catheters. Biocompatibility test results can be found in K955886. Biocompatibility testing was performed in compliance with ISO Standard 10993.

VII. Summary of Substantial Equivalence:

Jupiter PTA Catheters are substantially equivalent to the predicate devices. Jupiter PTA Catheters are similar in design, construction, indications for use, and performance characteristics as compared to commercially available PTA Catheters.