PREMARKET NOTIFICATION 510(k)
Cordis Corporation
4F Nylex Angiographic Catheter
Modification

0-000015

K962759

OCT 10 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Diagnostic Intravascular Catheter and Percutaneous Catheter

Proprietary Name: Cordis 4F Nylex™ Angiographic Catheter

II. Name of Predicate Devices

Cordis Corporation 4F Nylex Angiographic Catheter

Cordis Corporation 4F Infiniti Angiographic Catheter

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

The Cordis 4F Nylex Angiographic Catheters are intended for the delivery of radiopaque contrast medium to selected sites in the vasculature. The catheter is a 4F diameter single lumen catheter with a radiopaque tip.

VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on the materials used for the Cordis Corporation 4F Nylex Angiographic Catheters per ISO 10993-1.

VII. Summary of Substantial Equivalence

The Cordis 4F Nylex Angiographic Catheters are similar in design, construction, indication for use and performance characteristics to other commercially available angiographic catheters.