

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

K960975

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Diagnostic Intravascular Catheter and Percutaneous Catheter

Proprietary Name: Cordis 4F Infiniti™ Angiographic Catheter

II. Name of Predicate Devices

Cordis Corporation 4F Nylex Angiographic Catheter (K930479)

Cordis Corporation Paragon Angiographic Catheter (K921310/A)

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 Infiniti Angiographic Catheters are intended for the delivery of radiopaque contrast medium to selected sites in the vascular system. The catheter is 4F in diameter with a braided proximal shaft and radiopaque tip.

VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on the materials used for the Cordis Corporation Infiniti Angiographic Catheters.

VII. Summary of Substantial Equivalence

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

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