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**PREMARKET NOTIFICATION 510(k)
Cordis Corporation
Cinch® QR Steerable Guidewire Extension**

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Provisions

Common or Usual Name: Catheter Guide Wire (Accessory)
Proprietary Name: Cordis CINCH® QR Steerable Guidewire Extension

II. Name of Predicate Devices

CINCH® 3 Steerable Guidewire Extension

III. Classification

Catheter Guide Wire Accessory, Class II - 21 CFR 870.1330

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 CINCH® QR Steerable Guidewire Extension is designed to extend Cordis Steerable Guidewires so that a catheter can be exchanged for another catheter.

The CINCH® QR Steerable Guidewire Extension is a flexible stainless steel wire coated with DURAGLIDE™. The extension is 145 cm long and has a shaft diameter of 0.014 inches.

VI. Biocompatibility

Biocompatibility testing was not repeated since the CINCH® QR and the currently marketed CINCH® 3 (K914863) Steerable Guidewire Extensions are made of the same materials. The DURAGLIDE™ coating and method of application have also been cleared for use with the WIZDOM™ Steerable Guidewire (K953760).