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**PREMARKET NOTIFICATION 510(k)**  
**Cordis Endovascular Systems, Inc.**  
**CES Infusion Catheters**  
**Modification**

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**I General Provisions:**

Common or Usual Name: Diagnostic, Intravascular Catheter

Proprietary Name: *CES Infusion Catheters*

**II Name of Predicate Devices**

1. Trade Name: TRANSIT® Infusion Catheter  
Manufacturer: Cordis Endovascular Systems, Inc.
2. Trade Name: RapidTRANSIT® Infusion Catheter  
Manufacturer: Cordis Endovascular Systems, Inc
3. Trade Name: Tracker Infusion Catheters  
Manufacturer: Target Therapeutics

**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**

*CES Infusion Catheters* are intended to be used as a mechanism for the infusion of various diagnostic and embolic agents into the peripheral, coronary and neurovasculatures.

**VI. Biocompatibility**

All appropriate biocompatibility tests were successfully performed on the *CES Infusion Catheters*.

**VII. Summary of Substantial Equivalence**

The *CES Infusion Catheters* are similar in its basic design, construction, indication for use and performance characteristics to other commercially available infusion catheters.