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# PREMARKET NOTIFICATION 510 (K)
# Cordis Endovascular Systems, Inc.
# TruFill PVA Particles
# Modification - September 13, 1996

## SUMMARY OF SAFETY AND EFFECTIVENESS

### I. General Provisions

Common or Usual Name: Artificial Embolization Device
Proprietary Name: TruFill™ PVA Particles

### II. Name of Predicate Devices

TruFill PVA Particles manufactured by Cordis Endovascular Systems, Inc (CES) 510(k) No. K951314, concurred on 8/8/95

Contour PVA manufactured by Interventional Therapeutics Corporation 510 (k) No. K944354, concurred 12/13/94

### III. Classification

Class III, Artificial Embolization Device, 84HCG, CFR 882.5950

### 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

TRUFILL PVA particles may be used for vascular occlusion of blood vessels within the neurovascular systems. They are intended for use in the endovascular management of arteriovenous malformations and neoplastic lesions when presurgical devascularization is desirable.

### VI. Biocompatibility

All appropriate biocompatibility tests were successfully performed on the TruFill PVA Particles.

### VII. Summary of Substantial Equivalence

The TruFill PVA are similar in their basic design, construction, indication for use and performance characteristics to other commercially available poly vinyl alcohol particles.