JUN 4 1998

K972881

0-00004

510(k) Summary of Safety and Effectiveness

General Provisions

Common names used for this device, include:

- Platinum Fibered Coils
- Microcoils or Minicoils

The CES Vascular Occlusion System, consists of:

- TruFill™ Pushable Coils (or CES Pushable Coils), and
- TruPush™ Embolic Coil Pusher (or CES Coil Pusher)

Predicate Devices

The predicate devices are listed in the table below.

Device	Company	510 (k) Number, Concurrence Date	Product Code
CES Pushable Coils	Cordis Endovascular Systems, Inc.	K964367, 1/30/97	HCG
Helix Shaped Coils with Dacron Fibers	Target Therapeutics	K913312, 1/08/91	HCG
Hilal Embolization Microcoil	Cook, Inc.	K901337, 11/09/90	HCG

Classification

Class III

Performance Standard

Performance standards have not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

Intended use

CES Pushable Coils may be used to reduce or block the rate of blood flow in vessels of the neurovasculature for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas and other vascular lesions of the brain, spinal cord and spine.

Device description

The CES Vascular Occlusion System consists of straight and shaped CES Pushable Coils (made from platinum alloy and synthetic fibers) and the CES Coil Pusher (with two radiopaque tip markers). The pushable coils are designed for use under fluoroscopy with microcatheters having a minimum 0.21" I.D.

Biocompatibility	All applicable biocompatibility tests were successfully performed on the CES Pushable Coils.
Summary of Substantial Equivalence	The CES Pushable Coils are substantially equivalent in design, materials, sterilization and indications for use to other commercially available occlusion devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 4 1998

Ms. Martine D. Schneider
Sr. Regulatory Affairs Associate
Cordis Endovascular
14000 N.W. 57th Court
Miami Lakes, Florida 33014

Re: K972881/S1
Trade Name: CES Vascular Occlusion System
Regulatory Class: III
Product Code: 84HCG
Dated: January 29, 1998
Received: January 30, 1998

Dear Ms. Schneider:

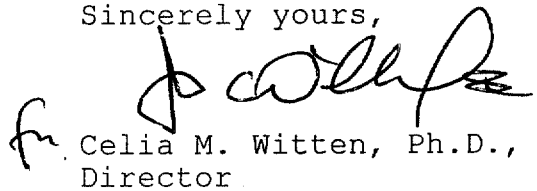
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number: K972881

Indications for Use Statement

CES Pushable Coils may be used to obstruct or reduce the rate of blood flow in vessels of the neurovasculature for the interventional management of arteriovenous malformations, arteriovenous fistulas and other vascular lesions of the brain, spinal cord, and spine.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972881