3/24/99

K983483
0-000029

Appendix A – Summary of Safety and Effectiveness, Continued

General Provisions

- The common names used for this device include:
- Platinum Fibered Coils
- Microcoils or Minicoils
- The Vascular Occlusion System consists of the following components:
- TRUFILL Pushable Coils
- TRUPUSH Coil Pusher

Predicate Devices

The predicate devices are listed in the table below:

Device	Manufacturer	510(k) Number, Concurrence Date	Product Code
Hilal Embolization Microcoil	Cook, Inc.	K901337, 11/9/90	HCG
Helix Shaped Coils with Dacron Fibers	Target Therapeutics	K901721, 1/8/91	HCG
Vascular Occlusion System	Cordis Endovascular Systems, Inc.	K964367, 1/30/97 K972881, 6/4/98	HCG

Classification

Class II

Performance Standard

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards.

Intended Use

The Vascular Occlusion System may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord, and spine.

Device Description

The Vascular Occlusion System consists of straight and shaped TRUFILL Pushable Coils (made from platinum allow and synthetic fibers) and the TRUPUSH Coil Pusher (with 1 or 2 radiopaque markers). The pushable coils are designed for use under fluoroscopy with microcatheters having a minimum 0.21" inner diameter.

Continued on next page

Appendix A – Summary of Safety and Effectiveness, Continued

Biocompatibility	All applicable biocompatibility testing was successfully performed for the Vascular Occlusion System.
Summary of Substantial Equivalence	The Vascular Occlusion System is substantially equivalent in design, materials, sterilization, and indications for use as other commercially available occlusion devices.[1]

[1] A statement of substantial equivalence to another product is required by 21 CFR 807.87, and relates to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 24 1999

Ms. Martine D. Martino
Sr. Regulatory Affairs Associate
Cordis Endovascular Systems, Inc.
14000 N.W. 57th Court
Miami Lakes, FL 33014

Re: K983483
Vascular Occlusion System
Regulatory Class: III (Three)
Product Code: 84 MCG
Dated: December 21, 1998
Received: December 24, 1998

Dear Ms. Martino:

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 legally marketed predicate 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 requirements, 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix C – Indications for Use Statement, Continued

Indications for Use Statement

The Cordis Endovascular Systems, Inc. Vascular Occlusion System may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for the interventional radiologic 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 ✓ OR Over-the-Counter Use____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K983483