Section 4 – Summary of Safety and Effectiveness 000010

510(k) Summary of Safety and Effectiveness

Trade Name	The trade name of this device is: TRUFILL DCS ORBIT™ Detachable Coil and TRUFILL® DCS Syringe, also known as the TRUFILL DCS ORBIT™ Detachable Coil System.
Common Name	The common name of the device is: Artificial Embolization Device.
Classification	These devices have been classified as Class III, per 21 CFR 882.5950 (84HCG), which have been classified within the Division of Cardiovascular, Respiratory, and Neurological Devices.
Performance Standards	There are no performance standards applicable under Section 514 of the Food, Drug and Cosmetic Act for Artificial Embolization Devices.
Applicant's Name	Cordis Neurovascular, Inc. 14000 NW 57 Court Miami, Florida 33014
Contact Person	Alina Caraballo Regulatory Affairs Manager (305) 786-313-6518 (305) 786-313-6480 (Fax)
Summary Date	April 21, 2003

Continued on next page

510(k) Summary of Safety and Effectiveness, Continued 000011

TRUFILL DCS ORBIT™ Detachable Coil Intended Use

The TRUFILL DCS ORBIT™ Detachable Coil is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be:

1. very high risk for management by traditional operative techniques, or,
2. inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

The TRUFILL DCS ORBIT™ Detachable Coil is also intended for arterial and venous embolizations in the peripheral vasculature.

TRUFILL® DCS Syringe Intended Use

The TRUFILL® DCS Syringe is indicated for use with the TRUFILL® family of Detachable Coils.

Comparative Characteristics

The table below compares the TRUFILL DCS ORBIT™ Detachable Coil System with the currently marketed device TRUFILL® DCS Detachable Coil System.

Characteristics	TRUFILL DCS ORBIT™ Detachable Coil System
Anatomical Sites	Same as predicate device
Intended Use	Same as predicate device
Method of Coil Attachment	Same as predicate device
Method of Coil Detachment	Same as predicate device
Detachment Feedback	Same as predicate device
Coil Shape Configurations	Same as predicate device (Added Mini Complex Configuration)
Coil Softness Configurations	Same as predicate device (Changed the nomenclature of the Basket Configuration to Standard)
Coil Wire Outer Diameter (in)	Same as predicate device
Primary Coil Diameter (in)	Same as predicate device
Secondary Coil Diameter (mm)	Same as predicate device
Coil Length (cm)	Same as predicate (Addition of 1.5 coil length)
Coil Material	Same as predicate device
Delivery System Usable Length (cm)	Same as predicate device
Delivery System Outer Diameter (in)	Downsized version of the predicate device
Delivery System Body Design	Same as predicate device
Radiopaque Marker Bands	Same as predicate device

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510(k) Summary of Safety and Effectiveness, Continued 000012

Predicate Devices The predicate device is listed in the table below:

Device	Company	510(k) Number / Concurrence Date	Product Code	Predicate for:
TRUFILL® DCS Detachable Coil System	Cordis Neurovascular, Inc.	K014041 / 3/7/02	HCG	Intended Use Embolic Coil Delivery System Detachment Mechanism Manufacturing Sterilization

Device Description

The TRUFILL DCS ORBIT™ Detachable Coil System is comprised of the TRUFILL DCS ORBIT™ Detachable Coil and TRUFILL® DCS Syringe.

- The TRUFILL DCS ORBIT™ Detachable Coil consists of a delivery system (delivery tube and coil introducer) and an embolic coil. The delivery tube segment comprises the body of the device and has the combined functionality of a guidewire and a mini infusion catheter. The coil introducer is a tube designed to protect the detachable embolic coil in the packaging dispenser and provide support for introducing the embolic coil into the infusion catheter. The embolic coil is the implantable segment of the device.

- The TRUFILL® DCS Syringe is used to generate a controlled pressure for preparation and detachment of the TRUFILL® family of Detachable Coils. The TRUFILL® DCS Syringe consists of a 25-cc barrel with a pressure gauge, a threaded plunger assembly with a locking wing mechanism, and a flexible high-pressure extension tube. The gauge faceplate is calibrated for three settings for use with the TRUFILL® family of Detachable Coils.

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510(k) Summary of Safety and Effectiveness, Continued

Non-Clinical Performance Data

The following in-vitro testing was conducted to support substantial equivalence to the predicate device.

Comparative Testing
Coil Softness / Stretch Resistance
Embolic Coil Placement Stability
Linear Stiffness Test
Distal Tip Angular Displacement
Flow Rate Test

The following in-vitro and animal testing was conducted to demonstrate the safety and effectiveness of the device, and to demonstrate that the device performs as it is intended.

Performance Testing
Embolic Coil Length Verification
Delivery System Outer Diameter Verification
Purge Reliability and Purge Confirmation
Delivery Tube / Introducer Zip / Unzip Verification
Embolic Attachment Strength Test
Distal Joint Pull Strength Test
Proximal (Transition) Joint Strength Test
Detachment Reliability Verification
Pushability Testing

Biocompatibility

All appropriate biocompatibility tests were successfully performed on the materials used to manufacture the TRUFILL DCS ORBIT™ Detachable Coil System.

Conclusion

Results of the in-vitro and animal testing demonstrated that the TRUFILL DCS ORBIT™ Detachable Coil System is substantially equivalent to the predicate device, TRUFILL® DCS Detachable Coil System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2003

Ms. Alina Caraballo
Regulatory Affairs Manager
Cordis Neurovascular, Inc.
P.O. Box 025700
Miami, Florida 33102-2700

Re: K030963
Trade/Device Name: TRUFILL DCS ORBIT™ Detachable Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: March 26, 2003
Received: March 27, 2003

Dear Ms. Caraballo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

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

Enclosure

K030963

0-000098

510(k) Number (if known): _____

Device Name: TRUFILL DCS ORBIT™ Detachable Coil System comprised of the TRUFILL DCS ORBIT™ Detachable Coil and TRUFILL® DCS Syringe

Indications for Use Statement

The TRUFILL DCS ORBIT™ Detachable Coil is intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be:

a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

The TRUFILL DCS ORBIT™ Detachable Coil is also intended for arterial and venous embolizations in the peripheral vasculature.

The TRUFILL® DCS Syringe is indicated for use with the TRUFILL® family of Detachable Coils.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030963