



DEC 15 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Amarilys Machado
Manager, Regulatory Affairs
Cordis Neurovascular, Inc.
14000 N.W. 57th Court
Miami Lakes, Florida 33014

Re: K053197

Trade/Device Name: Trufill DCS Orbit Detachable Coil System Line Extension
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: November 15, 2005
Received: December 5, 2005

Dear Ms. Machado:

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 (240) 276-0115. 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 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/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1
 CFF 20014
 Only the Native File to be Used
 Intended Use Statement

Page 1 of 1

Indications for Use

510(k) Number (if known):

Device Name: TRUFILL DCS ORBIT™ Detachable Coil and TRUFILL® DCS Syringe, also known as the TRUFILL DCS ORBIT™ Detachable Coil System

Indications For Use:

The TRUFILL DCS ORBIT™ Detachable Coil is indicated for embolizing certain intracranial aneurysms that, because of their morphology, 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
- 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.

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

Prescription Use
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
 (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
 and Neurological Devices**

510(k) Number: K052197