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CFF 10463867 Revision 02
Only the Native File to be Used

510(k) Summary of Safety and Effectiveness

Submitter's Name/Contact Person

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DEC - 7 2006

October 26, 2006

Trade Name / Common Name

The trade name is:

- The TRUFILL® DCS Detachable Coil System, comprised of the TRUFILL® DCS Detachable Coil and the TRUFILL® DCS Syringe or the TRUFILL® DCS Syringe II
- The TRUFILL DCS ORBIT™ Detachable Coil System, comprised of the TRUFILL DCS ORBIT™ Detachable Coil and the TRUFILL® DCS Syringe or the TRUFILL® DCS Syringe II

The common name for the TRUFILL® DCS and TRUFILL DCS ORBIT™ Detachable Coil Systems is: Artificial Embolization Device.

Classification

These devices have been classified as Class II, per 21 CFR 882.5950 (84HCG), which have been classified within the Division of Cardiovascular, Respiratory, and Neurological Devices.

Performance Standard

There are no performance standards applicable under Section 514 of the Food, Drug and Cosmetic Act for Artificial Embolization Devices.

Intended use

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

Device Description

The TRUFILL® DCS Syringe II consists of a 14-cc barrel with a pressure gauge, a threaded plunger assembly with a locking mechanism, and a flexible high-pressure extension tube with a male luer connector. The gauge faceplate is calibrated for use with the TRUFILL DCS ORBIT™ Detachable Coil and the TRUFILL® DCS Detachable Coil; i.e., the TRUFILL® family of Detachable Coils. The TRUFILL® DCS Syringe II is used to generate controllable pressure for preparation and coil detachment of the TRUFILL® family of Detachable Coils.

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

Device	Company	Product Code	510(k) Number	Predicate for: (if multiple predicates)
TRUFILL® DCS Syringe	Cordis Neurovascular, Inc.	HCG	K030963	• Intended Use • Design • Detachment Mechanism • Sterilization

Summary of Studies

The following table summarizes the *in-vitro* laboratory performance testing that was conducted to demonstrate the safety and effectiveness of the TRUFILL® DCS Syringe II and to demonstrate that the device performs as it is intended.

Performance and Safety Testing
Gauge Accuracy and Pressure Cycling
Luer Lock Connector Dimensional Verification
Chemical Compatibility Testing
Joint Pull Test
Device Integrity Test
Torque Test
Device Flush Particulate Test
Biocompatibility Testing

The following table summarizes the *in-vitro* testing that was conducted to validate the design of the TRUFILL® DCS Syringe II and to ensure that the device specifications conform to the user needs and intended use.

Design Validation Testing
Syringe Packaging
Purge and Detachment of TRUFILL® DCS Detachable Coils
Purge and Detachment of TRUFILL DCS ORBIT™ Detachable Coils
Syringe Integrity
Ability to Pressurize Syringe

Summary of Substantial Equivalence

The TRUFILL® DCS Syringe II is similar in its basic design, construction, indication for use, and performance characteristics to the predicate device, the TRUFILL® DCS Syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

DEC - 7 2006

Re: K063254
Trade/Device Name: TRUFILL® DCS Syringe II
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: II
Product Code: HCG
Dated: October 26, 2006
Received: October 27, 2006

Dear Amarilys 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K063254

Cordis®
a Johnson & Johnson company

Indications for Use

510(k) Number (if known): K063254

Device Name: TRUFILL® DCS Syringe II

Indications For Use:

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

Prescription Use _X__ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (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 K063254