5 510(K) SUMMARY

Applicant:

ev3® Inc.
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Irvine, CA 92618
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AUG 19 2008

Date: May 22, 2008

Contact Person:

Neelu Medhekar
Director, Global Regulatory Affairs

Proprietary Device Name: AXIUM™ DETACHABLE COIL SYSTEM

Common Device Name: Neurovascular Embolization Device
(21CFR 882.5950, Product Code HCG)

Classification: Class II

Predicate Devices:
Micro Therapeutics, Inc. FX Detachable Coil System (K060747) cleared 04/24/07 – *marketed as the ev3® AXIUM™ DETACHABLE COIL SYSTEM*
Micrus® Microcoil Delivery System (K073442) 02/26/2008
Boston Scientific/Target Therapeutics, Guglielmi Detachable Coil (K962503) cleared 09/20/1996

Manufacturer:

ev3® Neurovascular a division of ev3® Inc.
9775 Toledo Way
Irvine, CA 92618
USA

Note: Micro Theraputics Inc., does business as ev3® Neurovascular, which is a division of ev3® Inc. To simplify the product identification for the purposes of this submission, references will only be made to ev3® Inc.

5.1 Substantially Equivalent To:

The AXIUM™ DETACHABLE COIL SYSTEM is substantially equivalent to the Micro Therapeutics, Inc. FX Detachable Coil System (K060747) – *marketed as the ev3® AXIUM™ DETACHABLE COIL SYSTEM*, Micrus® Microcoil Delivery System (K073442), and the Boston Scientific/Target

Therapeutics, Guglielmi Detachable Coil (K962503) in terms of intended use, design, specifications, and materials. These systems are all indicated for use in the embolization of aneurysms. The predicate devices, Micrus® Microcoil Delivery System (K073442), and the Boston Scientific/Target Therapeutics, Guglielmi Detachable Coil (K962503) are indicated for neurovascular embolizations as well as embolizations in the peripheral vasculature.

The AXIUM™ DETACHABLE COIL SYSTEM uses the same design, methods and materials in construction, packaging and sterilization as its predicates. The modification to the indications use statement has not altered the fundamental scientific technology of the AXIUM™ devices.

5.2 Description of the Device Subject to Premarket Notification:

The AXIUM™ DETACHABLE COIL SYSTEM consists of a platinum coil secured to a composite delivery wire and is compatible with a 2-marker band micro catheter and a mechanical detachment system. The AXIUM™ coil configurations include bare platinum, PGLA laced platinum and Nylon laced platinum coils.

The AXIUM™ DETACHABLE COIL SYSTEM consists of three components:
1- Implantable Coil,
2- Implant Delivery Pusher,
3- Instant Detacher (called the LRS (Linear Release System) actuator in K060747). The Instant Detacher is packaged and sold separately.

This submission expands the indications for use statement to include arterial and venous embolizations in the peripheral vasculature. This indication is discussed further in Section 10.

5.3 Indications for Use:

The AXIUM™ DETACHABLE COIL SYSTEM is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The AXIUM™ DETACHABLE COILS are also indicated for arterial and venous embolizations in the peripheral vasculature.

5.4 Performance Data:

Bench data were generated to support the original FX Detachable Coil System (K060747), and are valid as the subject of this submission is an expanded indication and there is no change to the fundamental scientific technology of the device. Subsequent to the submission of K060747, additional bench and animal testing was performed for the *AXIUM™ DETACHABLE COIL SYSTEM.* A summary of the bench data are presented in Section 18 and the animal data are presented in Section 19 of this submission.

The risk assessment documentation for the *AXIUM™ DETACHABLE COIL SYSTEM* was reviewed to assess any new or unique risks posed by the peripheral vascular indication. No new risks were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 2008

EV3® Inc.
c/o Ms. Neelu Medhekar
Director, Global Regulatory Affairs
9775 Toledo Way
Irvine, CA 92618

Re: K081465
Axium™ Detachable Coil System
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II (two)
Product Code: KRD
Dated: May 23, 2008
Received: May 27, 2008

Dear Ms. Medhekar:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE STATEMENT

510(k) No (if known): K081465

Device Name: AXIUM™ DETACHABLE COIL SYSTEM

Indications for Use:

The AXIUM™ DETACHABLE COIL SYSTEM is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The AXIUM™ DETACHABLE COILS are also indicated for arterial and venous embolizations in the peripheral vasculature.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 Cardiovascular Devices

510(k) Number K081465

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