K101570

JUL 13 2010

510(k) Summary

ev3 Occlusion Balloon Catheters

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. Submitter Information:

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618

Contact Person: Laurie Cartwright
Manager, Global Regulatory Affairs

Summary Date: 27 May 2010

II. Device Name

Proprietary:	HYPERGLIDE™ and HYPERFORM™
Common:	Occlusion Balloon Catheter
Classification:	II
Product Code:	MJN
CFR Section:	21 CFR 870.4450

III. Predicate Devices

The ev3 Occlusion Balloon Catheters are substantially equivalent to the previously cleared occlusion balloon catheters cleared under 510(k)s K990487, K001237, K010162, K011526, K011656, K021066, K090728, K091458, K092495 and K100063.

IV. Device Description

The ev3 Occlusion Balloon Catheters are single lumen, open-ended balloon catheters designed for advancement into the vasculature over a 0.010" guidewire. Balloon inflation is accomplished by advancement of the guidewire through the open distal end of the balloon, redirecting inflation media to the balloon through side holes in the catheter wall.

The Occlusion Balloon Catheters are available in diameters ranging from 3 to 7 mm and lengths ranging from 7 to 30 mm.

The devices are packaged in a sterile pouch and are intended for single use only.

V. Intended Use

The ev3 Occlusion Balloon Catheters are intended for use in the peripheral and neuro vasculature wherever temporary occlusion is desired as well as for balloon-assisted embolization of intracranial aneurysms.

VII. Nonclinical Data

No nonclinical data was included in this submission.

VIII. Clinical Data

No clinical or animal data were included in this submission.

IX. Conclusions

The ev3 Occlusion Balloon Catheters are substantially equivalent to the previously cleared EQUINOX, HYPERFORM, and HYPERGLIDE Occlusion Balloon Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Micro Therapeutics DBA ev3 Neurovascular
c/o Ms. Laurie Cartwright
Manager, Global Regulatory Affairs
9775 Toledo Way
Irvine, CA 92618

JUL 13 2010

Re: K101570
HyperGlide and HyperForm Occlusion Balloons
Regulation Number: 21 CFR§ 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II (Two)
Product Code: MJN
Dated: May 27, 2010
Received: June 4, 2010

Dear Ms. Cartwright:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K101570

Device Name: HYPERGLIDE™ and HYPERFORM™ Occlusion Balloon Systems

Indications for Use:

The ev3 Occlusion Balloon Catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These catheters offer a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow; the Occlusion Balloon Catheters may also be used in balloon-assisted embolization of intracranial aneurysms.

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)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101570