

K101570

**510(k) Summary**  
**ev3 Occlusion Balloon Catheters**

**JUL 13 2010**

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.



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.

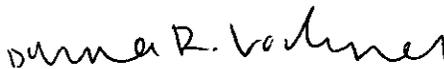
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21 CFR 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)**

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Danna R. Kachner*  
(Division Sign-Off)  
Division of Cardiovascular Devices

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