K090870

510(k) Summary

Applicant - Manufacturer Name and Address

Micro Therapeutics dba ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
Establishment Registration No. 2029214

MAY - 1 2009

Date March20, 2009

Contact Information

Tom Daughters
Director, Regulatory Affairs

Proprietary Device Model & Trade Name

Model: 105-5092-150SA, Echelon Micro Catheter (.014)
Model: 145-5092-150SA, Echelon Micro Catheter (.014 Pre-Shape)
Model: 190-5092-150SA, Echelon Micro Catheter (.014 Pre-Shape)
Model: 103-(5095) 1207 Syringe Adapter Accessory

Device Classification & Common Name

Classification Code: KRA, 21CFR Part 870.1210
Common Name: Catheter, Continuous Flush
Classification: Class II

Predicate Devices - 510(k) References

K030688 Model: Echelon Micro Catheter (.014)
K031992 Model: Echelon Micro Catheter (.010)
K042187 Models: Echelon Micro Catheter (.010, .014) - Pre-Shaped Tips
K051990 Models: Echelon Catheters (.010, .014) - Revised Contraindication

Description of the Device Subject to Premarket Notification

The MTI Echelon™ Micro Catheter is an end-hole, single-lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The catheter has a semi-rigid proximal shaft which transitions into the flexible distal shaft to facilitate the advancement of the catheter in the anatomy. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the catheter is coated to increase lubricity.

The Echelon Micro Catheter is packaged with an ev3 Syringe Adapter. This device, attached to an ev3 1ml syringe filled with Onyx®, will reduce the dead space within the micro catheter luer hub. Reducing the dead space within the hub

is intended to minimize the potential mixing of Onyx® and DMSO in the hub of the catheter during connection and injection.

Indications for Use

The Echelon Micro Catheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and or diagnostic materials such as contrast media.

Performance Data

Because the Echelon catheter itself has not changed, the scope of design verification focused on performance and compatibility of the Syringe Adapter accessory device. Verification studies included:

Dimensional	Catheter Dead Space Volume
Luer Fitting Integrity	Radiopacity of Onyx Injection
Onyx Infusion Pressure	Static Burst Pressure

Substantial Equivalence

The risk assessment for the Echelon catheter and the Syringe Adapter accessory was reviewed to identify any new or unique risks. No new risks were identified. The indications for use, the scientific technology and the performance data demonstrate the Echelon Microcatheter with the Syringe Adapter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2009

Micro Therapeutics dba ev3 Neurovascular
c/o Mr. Tom Daughters
Director, Regulatory Affairs
9775 Toledo Way
Irvine, CA 92618

Re: K090870
Echelon Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: March 20, 2009
Received: March 30, 2009

Dear Mr. Daughters:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

Statement of Indications for Use

Indications for Use

510(k) Number (if known): K090870

Device Name: Echelon Micro Catheter

Indications for Use:

The Echelon Micro Catheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and or diagnostic materials such as contrast media.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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 K090870

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