3. 510(K) SUMMARY

DEC - 9 2009

Applicant - Manufacturer Name and Address
Micro Therapeutics dba ev3 Neurovascular
9775 Toledo Way
Irvine, CA 92618
Establishment Registration No. 2029214

Date: December 04, 2009

Contact Information
Laura Heaton
Senior Regulatory Affairs Specialist
Main: (949) 837-3700
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Trade Names
Rebar™ Micro Catheter
Ultraflow™ HPC Flow Directed Micro Catheter
Nautica™ Micro Catheter
Marathon™ Flow Directed Micro Catheter
Echelon™ Micro Catheter

Device Classification & Common Name

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

Predicate Devices - 510(k) References

Rebar™-14 Micro Catheter	K993672
Rebar™-18, Rebar™-27 Micro Catheter	K001966
Rebar™-10 Micro Catheter	K002723
Ultraflow™ HPC Flow Directed Micro Catheter	K024118
Nautica™ Micro Catheter	K024122
Marathon™ Flow Directed Micro Catheter	K034036
Echelon™-14 Micro Catheter	K030688
Echelon™-10 Micro Catheter	K031992
Echelon™-10, Echelon™-14 Tip Shape Micro Catheter	K042187
Echelon™ Micro Catheter	K051990

Description of the Device Subject to Premarket Notification

The MTI/ev3 micro catheters are single-lumen, end-hole catheters designed for the sub selective infusion of physician-specified therapeutic agents such as embolization materials and diagnostic materials such as contrast media in tortuous, distal vessels. The catheters have a semi-rigid proximal shaft and a highly flexible distal shaft to facilitate the advancement of the catheter in the anatomy. The proximal end of the catheters incorporates a standard luer adapter to facilitate the attachment of accessories. The catheters have single or dual radiopaque markers at the distal end to

facilitate fluoroscopic visualization. The outer surfaces of the catheters are coated to increase lubricity.

Indications for Use

The Rebar Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.

The UltraFlow HPC Flow Directed Micro Catheter is intended for the controlled selective infusion of physician-specified pharmacologic agents or contrast media into the distal vasculature of the peripheral and neuro anatomy. It is not intended for use in the coronary vasculature.

The Nautica Micro Catheter is intended to access peripheral and neurovasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media. Not intended for use in the coronary vasculature.

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

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

Performance Data

The micro catheter devices have not changed; therefore there is no performance data included in this submission. The Instructions for Use have been revised to remove the pediatric and neonatal contraindication.

Substantial Equivalence

The devices have not changed and no new risks have been identified. The indications for use demonstrate the MTI/ev3 Micro Catheters are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

eV3 Inc.
c/o Ms. Laura Heaton
Senior Regulatory Affairs Specialist
9775 Toledo Way
Irvine, CA 92618

DEC - 9 2009

Re: K093750
Rebar™ Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: December 4, 2009
Received: December 7, 2009

Dear Ms. Heaton:

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 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 Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. STATEMENT OF INDICATIONS FOR USE

Indications for Use

510(k) Number (if known): K093750

Device Name: Rebar™ Micro Catheter

Indications for Use: The Rebar Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.

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

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Donna R. Richards

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093750

Indications for Use

510(k) Number (if known): K093750

Device Name: UltraFlow™ HPC Flow Directed Micro Catheter

Indications for Use: The UltraFlow HPC Flow Directed Micro Catheter is intended for the controlled selective infusion of physician-specified pharmacologic agents or contrast media into the distal vasculature of the peripheral and neuro anatomy. It is not intended for use in the coronary vasculature.

Prescription Use ___X___ 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)

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Indications for Use

510(k) Number (if known): K093750

Device Name: Nautica™ Micro Catheter

Indications for Use: The Nautica Micro Catheter is intended to access peripheral and neurovasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media. Not intended for use in the coronary vasculature.

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

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K093750

Device Name: Marathon™ Micro Catheter

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known): K093750

Device Name: Echelon™ Micro Catheter

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

Prescription Use ___X___ 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)

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