4. 510(k) Summary

Prepared July 21, 2005

TRADE NAME **GENERIC NAME** **CLASSIFICATION**	Echelon™ Micro Catheter Catheter, Continuous Flush and Syringe Class II (21 CFR 870.1210) and Class II 21 CFR870.4450
SUBMITTED BY	Micro Therapeutics, Inc. Contact: Marilyn R. Pourazar 2 Goodyear Manager, Regulatory Affairs Irvine, CA 92618 (949) 837-3700 x1293
PREDICATE DEVICE(S)	MTI K993672 MTI Rebar® Micro Catheter decision date 4-Jan-2000 MTI K030688, MTI Echelon Micro Catheter decision date March 27, 2003 MTI K031992, MTI Echelon Micro Catheter decision date August 3, 2003
DEVICE DESCRIPTION	The Echelon Micro Catheter is an endhole, single-lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of accessories. 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.
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.
TESTING	*In-vitro* performance testing of the MTI Echelon™ Micro Catheter included dimensional inspection, visual analysis, tensile strength tests, tip tensile strength, burst pressure tests, flow rate tests, torque tests, tip reshape-ability /retention, tip offset distances measurement, tip length measurement specification, guidewire friction, coil friction and performance under simulated conditions. The biocompatibility of the MTI Echelon™ Micro Catheter was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the catheter was tested as an external communicating, blood contact, limited exposure (<24 hrs) device.
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The MTI Echelon™ Micro Catheters are substantially equivalent to the predicate devices in intended use and principles of operation.

5. Truthful and Accuracy Certification

Pursuant to 21 CFR 807.87(j), I Marilyn R Pourazar, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Regulatory Affairs Manager of Micro Therapeutics, Inc., and in reliance thereupon, the data and information submitted in this Premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

Marilyn R. Pourazar
Manager, Regulatory Affairs
Micro Therapeutics, Inc.

7-20-05
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 4 2006

Micro Therapeutics, Inc
c/o Ms. Marilyn R. Pourazar
Manager of Regulatory Affairs
2 Goodyear
Irvine, CA 92618

Re: K051990
Trade Name: MTI Echelon Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Infusion Catheter
Regulatory Class: II (two)
Product Code: KRA
Dated: November 30, 2005
Received: December 01, 2005

Dear Ms. Pourazar:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 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

Indications for Use

510(k) Number (if known): K051990

Device Name:

Indications For Use:
The MTI 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 807 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. Kuchner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051990