K042187



SEP - 2 2004

# 4. 510(k) Summary

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| **TRADE NAME**<br>**GENERIC NAME**<br>**CLASSIFICATION** | Tip-Shape Echelon™ Micro Catheter<br>Catheter, Continuous Flush<br>Class II (21 CFR 870.1210) and Class II (21 CFR 870.4450) |
| **SUBMITTED BY** | Micro Therapeutics, Inc.<br>2 Goodyear<br>Irvine, CA 92618<br><br>Marilyn R. Pourazar<br>Regulatory Affairs<br>(949) 837-3700 x293 |
| **PREDICATE DEVICE(S)** | MTI Echelon™ Micro Catheter (K030688)<br>MTI Echelon™ Micro Catheter (K031992) |
| **DEVICE DESCRIPTION** | The Tip-shape 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.<br>This is the same intended use as predicate devices Echelon Micro Catheter K030688 and K031992. |
| **TESTING** | *In-vitro* performance testing of the MTI Tip Shape Echelon™ Micro Catheter included Dimensional and Visual Analysis, Tip Tensile Strength, Pressure Testing, Guidewire Friction, Coil Friction, Tip Reshape-ability and Retention, Tip offset distances measurement and Tip length measurement specification.<br>The biocompatibility of the MTI Tip Shape 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 Tip Shape Echelon™ Micro Catheter is substantially equivalent to the predicate devices in intended use and principles of operation. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2004

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

Re: K042187
Tip-Shape Echelon Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II (two)
Product Code: KRA
Dated: August 6, 2004
Received: August 12, 2004

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 (301) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

Diana R. Vachner

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): **K042187**

Device Name: **MTI Tip-Shape Echelon™ Micro Catheter**

Indications For Use:

The **Tip-Shape 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____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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)

Donna R. Kuhnel

(Division Sign-Off)
Division of Cardiovascular Devices

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