K024118



FEB 0 3 2003

# 4. 510(k) Summary

**Prepared December 13, 2002**

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| **TRADE NAME** | UltraFlow™ HPC Flow Directed Micro Catheter |
| **GENERIC NAME** | Flow Directed Micro Catheter |
| **CLASSIFICATION** | Class II (21 CFR 870.1210) |
| **SUBMITTED BY** | Micro Therapeutics, Inc.<br>2 Goodyear<br>Irvine, CA 92618 |
| **CONTACT** | Bill Hyatt<br>Regulatory Affairs<br>(949) 837-3700 |
| **PREDICATE DEVICE(S)** | Modified FlowRider™ Flow Directed Micro Catheter (K010004), cleared February 13, 2001. |
| **DEVICE DESCRIPTION** | The UltraFlow™ HPC Flow Directed Micro Catheters are single-lumen, endhole catheters designed for the subselective infusion of physician-specified pharmacologic agents or 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 catheter incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter has a radiopaque marker at the distal end to facilitate fluoroscopic visualization. The outer surfaces of the catheter are coated to increase lubricity. The stylet accompanying the catheter is used to increase the rigidity of the distal section during introduction into the guiding 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. |
| **TESTING** | Selected *in-vitro* performance testing of the MTI UltraFlow™ HPC Micro Catheter were performed to verify the minor product changes. These tests included the following:<br>• Biocompatibility<br>• Angiographic visualization<br>• Dimensional verification<br>• Functional performance. |
| **SUMMARY OF SUBSTANTIAL EQUIVALENCE** | The UltraFlow™ HPC Flow Directed Micro Catheter is the same device as the Modified FlowRider™ Flow Directed Micro Catheter (K010004). This submission has been made to change the device name as it appears on the CDRH database for Premarket Notification decisions.<br>Minor enhancements to the design would normally have required letters to file based upon FDA's guidance document "Deciding When To Submit a 510(k) for a change to an Existing device", January 10, 1997 and are being presented here for information purposes only. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 3 2003

Mr. Bill Hyatt
Manager, Regulatory Affairs
Micro Therapeutics, Inc.
2 Goodyear
Irvine, CA 92618

Re: K024118
Trade/Device Name: UltraFlow™ HPC Flow Directed Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: Class II
Product Code: KRA
Dated: January 14, 2003
Received: January 16, 2003

Dear Mr. Hyatt:

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) 594-4586. 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 6. Indications for Use Statement

**510(k) Number (if known):** _____

**Device Name:** MTI 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.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

_____ _____ _____ _____ _____ _____

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** X **OR** **Over the Counter Use**_____
**(Per 21 CFR 801.109)**

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K084182