K980104

APR 10 1998

MICRO THERAPEUTICS, INC.

510(k) Summary of Safety and Effectiveness

Flow Rider™ Flow Directed Micro Catheter

Prepared January 8, 1998

Trade Name:	Flow Rider™ Flow Directed Micro Catheter		
Generic Name:	Percutaneous Intravascular Catheter	**Classification:**	Class II
Submitted By:	Micro Therapeutics, Inc. 1062-F Calle Negocio San Clemente, CA 92673	**Contact:**	Tom Daughters Regulatory Affairs (714) 361-0610

Predicate Devices

Target Spinnaker™ Flow Directed Infusion Catheter, K965189

Balt Magic™ Infusion Catheter, K923368

Device Description

The Flow Rider Flow Directed Micro Catheter is a single lumen infusion catheter designed to be flow directed into the distal vasculature. The Flow Rider Flow Directed Micro Catheter has a hydrophilic coating to provide lubricity for navigation of vessels. A standard luer lock adapter on the proximal hub is used for the attachment of accessories. The catheter tip is indicated by a radiopaque marker to facilitate fluoroscopic visualization.

Intended Use

The catheter is intended to be used for the controlled selective infusion of physician specified pharmacologic agents or contrast media into the distal vasculature of the peripheral and neuro anatomy.

Testing

Biocompatibility testing was performed on the Flow Rider Flow Directed Micro Catheter in accordance with the International Standard for the Biological Evaluation of Medical Devices, Part 1: Guidance on Selection of Tests (ISO 10993-1:1992(E)). Results of the tests showed that the device passed Biocompatibility testing and is suitable for its application.

Physical testing of the product included dimensional inspection, tensile strength tests, burst pressure tests, flow rate tests, torque tests and performance under simulated conditions. All testing of the product yielded acceptable results.

Animal studies were performed to assess the performance of the Flow Rider Catheter. The studies demonstrated that the Flow Rider Catheter is substantially equivalent to the predicate devices.

Summary of Substantial Equivalence

The Flow Rider Flow Directed 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

APR 10 1998

Mr. Tom Daughters
Regulatory Affairs
Micro Therapeutics, Inc.
1062-F Calle Negocio
San Clemente, CA 92673

Re: K980104
Trade Name: Flow Rider™ Flow Directed Micro Catheter
Regulatory Class: II
Product Code: KRA
Dated: January 9, 1998
Received: January 13, 1998

Dear Mr. Daughters:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: **Flow Rider™ Flow Directed Micro Catheter**

Indications for Use:

The catheter is intended to be used for the controlled selective infusion of physician specified pharmacologic agents or contrast media into the distal vasculature of the peripheral and neuro anatomy.

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** **Over the Counter Use** _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980104