

Micro Therapeutics, Inc.
 Traditional 510(k)
 Marathon™ Flow Directed Micro Catheter
 December 24, 2003

FEB 13 2004

4. 510(k) Summary

Prepared December 24, 2003

TRADE NAME	Marathon™ Flow Directed Micro Catheter		
GENERIC NAME	Flow Directed Micro Catheter		
CLASSIFICATION	Class II (21 CFR 870.1210)		
SUBMITTED BY	Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618	CONTACT	Bill Hyatt Regulatory Affairs (949) 837-3700
PREDICATE DEVICE(S)	<ul style="list-style-type: none"> • UltraFlow™ HPC Flow Directed Micro Catheter (K024118), cleared February 3, 2003 • Echelon™ Over the Wire Micro Catheter (K030688), cleared March 28, 2003 		
DEVICE DESCRIPTION	<p>The Marathon™ Micro Catheters are single-lumen, endhole catheters designed for the subselective infusion of physician specified therapeutic agents or contrast media in tortuous, distal vessels. The catheter has 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.</p>		
INDICATIONS FOR USE	<p>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.</p>		
TESTING	<p>MTI performed <i>in vitro</i> and <i>in vivo</i> tests to verify and validate product design. Tests included the following:</p> <ul style="list-style-type: none"> • Biocompatibility • Angiographic visualization • Dimensional verification • Functional performance 		
SUMMARY OF SUBSTANTIAL EQUIVALENCE	<p>The Marathon Flow Directed Micro Catheter has</p> <ol style="list-style-type: none"> (1) substantially equivalent device and embolic material compatibility to predicate devices (UltraFlow and Echelon Micro Catheters), including DMSO and Onyx® compatibility, (2) substantially equivalent flow directability and accessibility to the predicate UltraFlow HPC Flow Directed Micro Catheter device, (3) substantially equivalent materials and construction to the predicate devices (distal shaft = Echelon, proximal shaft = UltraFlow), and (4) an identical intended use to the predicate device (Echelon). 		



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Micro Therapeutics, Inc
c/o Ms. Marilyn Pourazar
2 Goodyear
Irvine, CA 92618

Re: K034036
Marathon™ Flow Directed Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: December 24, 2003
Received: December 29, 2003

Dear Ms. Pourazar:

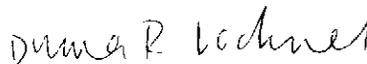
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4646. 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

