JUN 1 8 2002

Attachment 4

K021066

510(k) Summary

Prepared March 28, 2002

TRADE NAME	HyperGlide™ Occlusion Balloon Catheter
GENERIC NAME	Occlusion Balloon Catheter
CLASSIFICATION	Class II (21 CFR 870.4450)
SUBMITTED BY	Micro Therapeutics, Inc. CONTACT Tom Daughters 2 Goodyear Regulatory Affairs Irvine, CA 92618 (949) 837-3700
PREDICATE DEVICE	MTI Equinox™ Occlusion Balloon Catheter MTI HyperGlide™ Occlusion Balloon Catheter
DEVICE DESCRIPTION	The HyperGlide™ Occlusion Balloon Catheter is a single lumen balloon catheter with at maximum outer diameter of 2.8F tapering to 2.2F at the distal tip. The distal end of the catheter has a non-detachable low inflation pressure compliant balloon. The catheter is designed to track over the MTI 0.010" guidewire, and requires insertion of the guidewire to occlude the catheter shaft lumen to allow inflation of the balloon. Two platinum markers provide angiographic visualization of the balloon length and facilitate intravascular placement of the balloon prior to inflation. The catheter shaft is hydrophilically coated to assist catheter advancement within the vasculature. The HyperGlide catheter is supplied sterile for single use or as a system, which includes the required 0.010" guidewire.
INDICATIONS FOR USE	The MTI Occlusion Balloon Catheter is indicated for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. The MTI Occlusion Balloon Catheter offers a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow.
TESTING	Performance testing of the HyperGlide catheter was conducted in accordance with ISO 10555 Sterile, Single Use Intravascular Catheters- Parts 1 and 4 and Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters , Lasers, and Intravascular Stents (Draft May 1995).
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The MTI HyperGlide™ Occlusion Balloon Catheter is substantially equivalent to the predicate device in intended use, principles of operation and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2002

Mr. Tom Daughters
Director of Regulatory Affairs
Micro Therapeutics, Inc.
2 Goodyear
Irvine, CA 92618

Re: K021066
Trade/Device Name: MTI HyperGlide™ Occlusion Balloon Catheter
Regulation Number: 870.4450
Regulation Name: Vascular clamp
Regulatory Class: II
Product Code: MJN
Dated: March 28, 2002
Received: April 2, 2002

Dear Mr. Daughters:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Milhenn

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021066

Attachment 2

Indications for Use Statement

510(k) Number (if known): _____

Device Name: MTI HyperGlide™ Occlusion Balloon Catheter

Indications for Use: The MTI HyperGlide™ Occlusion Balloon Catheter is indicated for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. The MTI Modified Occlusion Balloon Catheter offers a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow.

(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)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

K021066