JUN 2 0 2001

 K011656

Attachment 6

510(k) Summary

Prepared May 24, 2001

TRADE NAME	Unknown
GENERIC NAME	Occlusion Balloon Catheter
CLASSIFICATION	Class II (21 CFR 870.0)
SUBMITTED BY	Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618
CONTACT	Eben Gordon Regulatory Affairs (949) 837-3700
PREDICATE DEVICE	MTI Equinox™ Occlusion Balloon Catheter
DEVICE DESCRIPTION	The HyperForm™ Occlusion Balloon Catheter is a single lumen tapered catheter with a non-detachable low inflation pressure compliant balloon attached to the distal end of the catheter. 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 HyperForm catheter is supplied sterile for single use 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	Biocompatibility of the HyperForm catheter was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the HyperForm catheter when tested as an external communicating, blood contact, short duration (<24 hrs.) device. Performance testing of the HyperForm catheter was conducted in accordance with ISO 10555 Sterile, single use intravascular catheters- Parts 1 and 4. Tests included dimensional verification, balloon compliance and integrity, catheter tensile strength, torque strength, flexibility, trackability, and coating integrity. Test results demonstrate that the device meets or exceeds the requirements of these standards and performs substantially equivalent to the predicate device.
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The MTI HyperForm™ Occlusion Balloon Catheter is substantially equivalent to the predicate device 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

JUN 2 0 2001

Mr Eben Gordon
Director of Regulatory Affairs and Quality Assurance
Micro Therapeutics, Inc.
2 Goodyear
Irvine, CA 92618

Re: K011656
Trade Name: MTI HyperForm™ Occlusion Balloon Catheter
Regulation Number: 870.4450
Regulation Class: II (two)
Product Code: MJN
Dated: May 24, 2001
Received: May 29, 2001

Dear Mr. Gordon:

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) 594-4648. 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 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Attachment 2

Indications for Use Statement

510(k) Number (if known): K011656

Device Name: **MTI HyperForm™ Occlusion Balloon Catheter**

Indications for Use: **The MTI HyperForm™ Occlusion Balloon Catheter is indicated for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. The MTI HyperForm™ 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 ✓ **OR** **Over the Counter Use**_____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011656