

AUG 31 1999

K990487

**Equinox Occlusion Balloon - 510(k) K990487  
Additional Information Submission**

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**510(k) Summary of Safety and Effectiveness  
Equinox™ Occlusion Balloon Catheter  
Prepared June 4, 1999**

|                      |  |                        |   |
|----------------------|--|------------------------|---|
| <b>TRADE NAME:</b>   | Equinox™ Occlusion Balloon System                          | <b>CLASSIFICATION:</b> | Class II  |
| <b>GENERIC NAME:</b> | Occlusion Balloon Catheter                                 | <b>CONTACT:</b>        | Tom Daughters<br>Regulatory Affairs<br>(949) 837-3700 |
| <b>SUBMITTED BY:</b> | Micro Therapeutics, Inc.<br>2 Goodyear<br>Irvine, CA 92618 |                        |   |

**PREDICATE DEVICES**

Target Therapeutics, Inc (BSC). Endeavor Coaxial Catheter

**DEVICE DESCRIPTION**

The Equinox™ Occlusion Balloon Catheter is a single lumen balloon catheter with a 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 SilverSpeed™ 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 Equinox catheter is supplied sterile for single use as a system which includes the required SilverSpeed .010" Guidewire and a rotating hemostatic valve.

**INDICATIONS FOR USE**

The Micro Therapeutics, Inc. Occlusion Balloon Catheter is designed for use in blood vessels 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 Equinox catheter was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the Equinox catheter when tested as an external communicating, blood contact, short duration (<24 hrs.) device.

Performance testing of the Equinox 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 Equinox™ 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

AUG 31 1999

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

Re: K990487

Trade Name: Equinox™ Occlusion Balloon System  
Regulatory Class: II  
Product Code: MJN  
Dated: June 4, 1999  
Received: June 9, 1999

Dear Mr. Daughters:

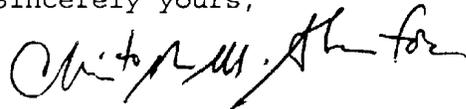
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. 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, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Equinox Occlusion Balloon - 510(k) K990487  
Additional Information Submission**

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510(k) Number (if known):     K990487    

Device Name: **Equinox™ Occlusion Balloon System**

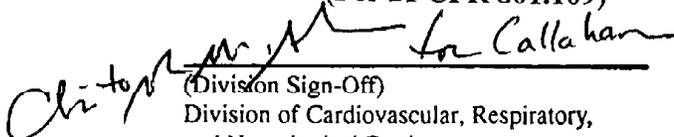
Indications for Use: **The Micro Therapeutics, Inc. Occlusion Balloon Catheter is designed for use in blood vessels where temporary occlusion is desired. The MTI Occlusion Balloon Catheter offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow.**

**(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

**Exhibit 1 Page: 5 of 7**

510(k) Number \_\_\_\_\_