FEB 6 1998

K973669

MICRO THERAPEUTICS, INC.

1062-F Calle Negocio San Clemente, CA 92673 Tel. 714-361- 0616 Fax 714- 361-0210

510(k) SUMMARY

Contact Person

Jack Gehrich
Vice President of Regulatory & Clinical Affairs

Trade Name

Over the Wire (OTW) Thrombolytic Brush Catheter

Common Name

Thrombectomy Catheter
Infusion Catheter

Classification Name

Percutaneous Catheter (per 21 CFR 870.1250)

Substantially Equivalent Devices

Thrombolytic Brush Catheter (Micro Therapeutics)

Description

The Micro Therapeutics, Inc. Over the Wire (OTW) Thrombolytic Brush Catheter is intended for the percutaneous dissolution of acute thrombus located in artificial arteriovenous (A-V) fistula. The OTW Thrombolytic Brush Catheter is designed to augment the area of interface between clot and pharmacologic agent by simultaneous thrombolysis and clot maceration. The integral system utilizes a catheter with proximal Y-connector, a soft brush attached at the distal end of a hollow drive shaft, and a hand-held battery-powered motor drive.

Intended Use

The Micro Therapeutics, Inc. Over the Wire (OTW) Thrombolytic Brush Catheter is intended for percutaneous dissolution of acute thrombus (i.e., less than two weeks old) located in arteriovenous (A-V) fistula utilizing a .035" guide wire for tracking and positioning within the fistula. The OTW Thrombolytic Brush Catheter is designed to augment the area of interface between clot and pharmacologic augment by simultaneous thrombolysis and clot maceration. Clinical studies demonstrate effective dissolution of thrombus in A-V grafts when this product is used in conjunction with urokinase. The OTW Thrombolytic Brush Catheter is not intended for use in native vessels. The device should not be used on patients with a history of significant pulmonary disease or pulmonary hypertension.

510(k) SUMMARY (cont.)

Technological Characteristics

This product is equivalent in *intended use*, as well as *dimensional characteristics, composition* and *function* to the legally marketed Thrombolytic Brush Catheter, (K963925) manufactured by Micro Therapeutics, Inc.

Summary of Studies

Performance Data

***In Vitro* Tests**

Sample sterile devices were subjected to extensive physical bench testing. In vitro tests were conducted which included dimensional measurements, bristle and wire cable strength characterization, motor drive integrity testing, catheter flow rates, bond strengths, burst pressure and performance under simulated conditions. Additionally, electromagnetic and patient safety tests were conducted by an independent laboratory to evaluate the electromagnetic and leakage current potential of the battery operated motor drive handle. Based on the results from these tests, it was concluded that the design performed equivalently to the predicate device and is suitable for its intended use.

***In Vivo* Tests**

In vivo animal tests were performed to assess the performance of the Micro Therapeutics, Inc. Over the Wire (OTW) Thrombolytic Brush Catheter to that of a predicate device. The animal studies demonstrated that the OTW Thrombolytic Brush Catheter performed the same as the predicate device for percutaneous administration of pharmacologicals for dissolution of thrombus located in A-V fistulas.

Biocompatibility Tests

All components tested per ISO 10993-1.

Conclusion: The Micro Therapeutics, Inc. Over the Wire (OTW) Thrombolytic Brush Catheter is substantially equivalent to the predicate device based on the results of laboratory and animal testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

FEB - 6 1998

Mr. Brian Strauss
Project Engineer
Micro Therapeutics, Inc.
1062-F Calle Negocio
San Clemente, CA 92673

Re: K973669
Over-the-Wire (OTW) Thrombolytic Brush Catheter
Regulatory Class: II (two)
Product Code: 74 MCW
Dated: January 7, 1998
Received: January 9, 1998

Dear Mr. Strauss:

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 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" (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/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

7

510(k) Number: K973669

Device Name: **Micro Therapeutics Over the Wire (OTW) Thrombolytic Brush Catheter**

Indications for Use:

The Micro Therapeutics, Inc. Over the Wire (OTW) Thrombolytic Brush Catheter is intended for percutaneous dissolution of acute thrombus located in arteriovenous (A-V) fistula. The Over the Wire (OTW) Thrombolytic Brush Catheter is designed to augment the area of interface between clot and pharmacologic augment by simultaneous thrombolysis and clot maceration. Clinical studies demonstrate effective dissolution of thrombus in A-V grafts when this product is used in conjunction with urokinase. The Over the Wire (OTW) Thrombolytic Brush Catheter is not intended for use in native vessels. The device should not be used on patients with a history of significant pulmonary disease of pulmonary hypertension.

If Micro Therapeutics, Inc. intends to recommend its Over the Wire (OTW) Thrombolytic Brush Catheter interface with specific pharmacological agents, Micro Therapeutics will notify the Food and Drug Administration. Micro Therapeutics, Inc. will not promote any such action until the Food and Drug Administration has reviewed and approved such action.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973669

(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)

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