

K963925

510(k) SUMMARY

Micro Therapeutics, Inc.
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San Clemente, CA 92673
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AUG - 8 1997

Contact Person

John L. Gehrich, Ph.D.
Vice President of Regulatory & Clinical Affairs

Trade Name

Thrombolytic Brush Catheter and Motor Drive

Classification Name

Graft Thrombectomy Catheter
Infusion Catheter

Substantially Equivalent Devices

Fogarty® Graft Thrombectomy Catheter (Baxter Corp.)
Mewissen Infusion Catheter (MediTech)
Amplatz Thrombectomy Device (Microvena)

Description

The Micro Therapeutics Thrombolytic Brush Catheter is intended for the percutaneous dissolution of thrombus located in artificial arteriovenous (A-V) grafts. The Micro Therapeutics 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 nylon brush attached to a stainless steel flexible drive cable, and a hand-held battery-powered motor drive.

Intended Use

The Micro Therapeutics Thrombolytic Brush Catheter is intended for percutaneous dissolution of acute thrombus (i.e., less than two weeks old) located in artificial arteriovenous (A-V) grafts. The Thrombolytic Brush Catheter is designed to augment the area of interface between clot and pharmacologic agent 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 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.

Technological Characteristics

This product is equivalent in intended use as well as dimensional characteristics, composition and function to the legally marketed Baxter Fogarty® Graft Thrombectomy Catheter, manufactured by Baxter Healthcare Corporation, as well as the MediTech Mewissen Infusion Catheter.

This product is equivalent in intended use as well as composition and function to the legally marketed Amplatz Thrombectomy Device, (K954205) manufactured by Microvena, Corporation.

Summary of Studies

Performance Data

In Vitro Tests

Sample devices were subjected to extensive physical bench testing. In vitro tests were conducted which included complete 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 offered a considerable safety margin in critical areas and is suitable for its intended use.

Radiopacity

The radiopacity of the Thrombolytic Brush Catheter is comparable to other vascular catheters. The materials used in the manufacture of the Thrombolytic Brush Catheter are the same as the predicate devices listed in the 510(k), utilizing medical grade plastic, stainless steel and radiopaque positioning markers. The stainless steel cable drive and brush tip of the Thrombolytic Brush Catheter are adequately visualized under fluoroscopy and the catheter body has a platinum alloy marker band at the distal tip. Adequate radiopacity was demonstrated in both the animal trial and in the clinical study by the ability of all investigators to visualize the device under fluoroscopy.

Biocompatibility Tests

Tests for biocompatibility of materials for the Micro Therapeutics Thrombolytic Brush Catheter were performed to establish that the materials used in the device met the qualifications for short-term use in the vascular system in accordance with ISO 10993-1. Biocompatibility testing was performed on sterile product. In determining biocompatibility test design, testing was selected as deemed appropriate for the type of tissue/device interface and the duration of patient exposure. The results of these tests demonstrate the toxicological safety of the Thrombolytic Brush Catheter for its intended use.

In Vivo Tests

In vivo animal tests were performed to assess ease of use, suitable flexibility/stiffness required, safety and efficacy.

Histologic examinations were performed both in the arterial and venous portion of the anastomosis as well as macro- and microscopic examination of sliced 3mm sections of lung. Animal studies were performed at the University of Illinois College of Medicine at Peoria in Peoria, Illinois. The study was approved by the Animal Research Committee of the above-mentioned institution and all studies were performed under GLP guidelines.

Animal studies demonstrated the Micro Therapeutics Thrombolytic Brush Catheter to be a safe and efficacious device for percutaneous administration of pharmacologicals for dissolution of thrombus located in artificial A-V grafts.

Results of Clinical Trials

Eighty-one patients with thrombosed artificial looped hemodialysis grafts were randomized at five institutions in the United States. Forty-five subjects were randomized to treatment with the Thrombolytic Brush Catheter and thirty-six were randomized to treatment with pulse-spray infusion. Initial success was defined as <20% residual thrombus in the graft. Following the lysis procedure (Thrombolytic Brush Catheter or pulse-spray infusion) patients underwent thrombectomy to remove residual clot and balloon angioplasty to treat stenotic lesions. Patients were followed for 4½ months post procedure to determine primary graft patency (the ability to dialyze with no further interventions). The results of this study are detailed in the table below.

Parameter	Thrombolytic Brush Treatment Group	Pulse-Spray Infusion Control Group	Statistical Comparison
Number of patients enrolled	45	36	n/a
Number of grafts treated	43	35	n/a
Duration of lytic procedure	17 minutes	28 minutes	Significant (p=.0001)
Residual thrombus after lytic procedure	6.5%	25.5%	Significant (p=.0001)
Urokinase dose used	215,435 Units	455,882 Units	Significant (p=.0001)
Heparin dose used	2,570 Units	4926 Units	Significant (p=.0001)
Acute success of lytic procedure Graft patent within 30 minutes	42/43 (98%)	15/35 (43%)	Significant (p=.0001)
Stenotic lesion visualized	41/41 (100%) (No Secondary Intervention 2 patients)	33/33 (100%) (No Secondary Intervention 2 patients)	Not Significant (p=1.000)
Thrombectomy performed to remove residual thrombus	14/41 (34%)	14/33 (42%)	Not Significant (p=.481)
PTA performed to treat stenotic lesion	41/41 (100%)	32/32 (100%) 1 Missing	Not Significant (p=1.000)
Residual thrombus after thrombectomy and/or PTA	2.2%	1.6%	Not Significant (p=.6607)
Duration of entire procedure	70 minutes	84 minutes	Not Significant (p=.1735)
Procedural success after all interventions ¹ Graft patent, no major complications	39/43 (91%)	34/35 (97%)	Not Significant (p=.621)
Successful dialysis after all interventions	34/39 (87%)	30/34 (88%)	Lifetable analysis: Not significant ³
Primary Patency at 3 months ²	16/38 (42%) (No follow-up 1 patient)	15/31 (48%) (No follow-up 3 patients)	Lifetable analysis: Not significant ³
Failures within 3 months (Rethrombosed/New Graft/Died/Transplant)	22/38 (58%) (No follow-up 1 patient)	16/31 (52%) (No follow-up 3 patients)	Lifetable analysis: Not significant ³
Primary Patency at 4½ months ²	14/38 (37%) (No follow-up 1 patient)	14/30 (47%) (No follow-up 4 patients)	Lifetable analysis: Not significant ³
Failures within 4½ months (Rethrombosed/New Graft/Died/Transplant)	24/38 (63%) (No follow-up 1 patient)	16/30 (53%) (No follow-up 4 patients)	Lifetable analysis: Not significant ³

¹Procedure Failures (4 treatment group, 1 control group) were not included in the Lifetable analyses for primary patency calculations.

²Patients who rethrombosed, had new grafts placed, died or received transplants were considered failures for Primary Patency at the time of rethrombosis, death or intervention and at the subsequent follow-up interval(s).

³Lifetable analyses demonstrate no statistically significant difference between treatment and control for primary patency during the 4½ month follow-up period.

Conclusion: Clinical data demonstrate the Thrombolytic Brush Catheter is a safe, effective and rapid alternative to pulse-spray thrombolysis for patients with thrombosed hemodialysis access grafts.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

John L. Gehrich, Ph.D.
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and Clinical Affairs
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San Clemente, California 92673

AUG - 8 1997

Re: K963925
Thrombolytic Brush Catheter and Motor Drive
Regulatory Class: II (two)
Product Code: MCW
Dated: May 20, 1997
Received: May 21, 1997

Dear Dr. Gehrich:

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 (Pre-market 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 requirement, 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,

A handwritten signature in cursive script that reads "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

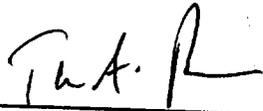
Enclosure

510(k) Number (if known):

Device Name: **Micro Therapeutics Thrombolytic Brush Catheter and Motor Drive**

Indications for Use:

The Micro Therapeutics Thrombolytic Brush Catheter is intended for percutaneous dissolution of acute thrombus (i.e., less than two weeks old) located in artificial arteriovenous (A-V) grafts. The Thrombolytic Brush Catheter is designed to augment the area of interface between clot and pharmacologic agent 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 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.



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of DCRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over the Counter Use