OCT 21 1999

K993257

MicroTherapeutics, Inc.

510(k) Summary of Safety and Effectiveness

SilverSpeed™ Hydrophilic Guidewire

Prepared September 23, 1999

Trade Name:	SilverSpeed™ Hydrophilic Guidewire (.014", .016" and .018")		
Generic Name:	Guidewire, Catheter	**Classification:**	Class II
Submitted By:	Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618	**Contact:**	Tom Daughters Regulatory Affairs (949) 837-3700

Predicate Devices

Micro Therapeutics, Inc. .010" SilverSpeed™ Hydrophilic Guidewire
B. Braun Guidewire Introducer & Guidewire Torque Device

Device Description

The SilverSpeed™ Hydrophilic Guidewire is a stainless steel guidewire with a radiopaque platinum distal coil. The guidewire is hydrophilically coated from the shapeable platinum coil up to the proximal 30cm of the guidewire. Included within the sterile pouch is a torque device to assist in guidewire manipulation and a guidewire introducer to ease the introduction of the guidewire into the catheter hub and/or hemostasis valve.

Intended Use

The guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

Testing

Biocompatibility of the guidewire has been verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the guidewire when tested as an external communicating, blood contact, short duration (<24 hrs.) device.

In-vitro performance testing of the guidewire included dimensional inspection, tensile strength, torque strength, flexibility, trackability, particulate and catheter compatibility tests. All testing of the product yielded acceptable results substantially equivalent to the predicate device.

Summary of Substantial Equivalence

The SilverSpeed Hydrophilic Guidewire and accessories are substantially equivalent to the predicate device in intended use and principle of operation.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1999

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

Re: K993257
Trade Name: SilverSpeed Hydrophilic Guidewire
Regulatory Class: II
Product Code: DQX
Dated: September 23, 1999
Received: September 29, 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. 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) 594-4586. 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" (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,

Wolf Sapirstein M.D

Wolf Sapirstein, M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k) Number (if known)	
Device Name	SilverSpeed Hydrophilic Guidewire
Indications for Use	The SilverSpeed Hydrophilic Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the peripheral, visceral and cerebral vasculature during diagnostic and/or therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801. 109)

Over-The-Counter Use_____

for Sapirstein

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K993257