

K982543

DEC 11 1998



## 510(k) Summary of Safety and Effectiveness

### SilverSpeed™ Hydrophilic Guidewire

Prepared December 9, 1998

<b>Trade Name:</b>	SilverSpeed™ Hydrophilic Guidewire		
<b>Generic Name:</b>	Guidewire, Catheter	<b>Classification:</b>	Class II
<b>Submitted By:</b>	Micro Therapeutics, Inc. 1062-F Calle Negocio San Clemente, CA 92673	<b>Contact:</b>	Tom Daughters Regulatory Affairs (949) 361-0616

#### Predicate Devices

Target Therapeutics, Inc. Dasher-10 Guidewire	B. Braun Guidewire Introducer
Target Therapeutics, Inc (BSC). Transend-10 Guidewire	B. Braun Guidewire Torque Device

#### Device Description

The SilverSpeed™ Hydrophilic Guidewire is a .010" diameter 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 devices.

In-vivo animal studies were performed to assess the performance of the guidewire in the neuro vasculature of rabbit and swine models. The studies demonstrated that the guidewire is substantially equivalent to the predicate devices.

#### Summary of Substantial Equivalence

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



DEC 11 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Tom Daughters  
Regulatory Affairs  
Micro Therapeutics, Inc.  
1062-F Calle Negocio  
San Clemente, CA 92673

Re: K982543

Trade Name: SilverSpeed™ Hydrophilic Guidewire  
Regulatory Class: II  
Product Code: DQX  
Dated: November 5, 1998  
Received: November 9, 1998

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 (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 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 pre-market 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,



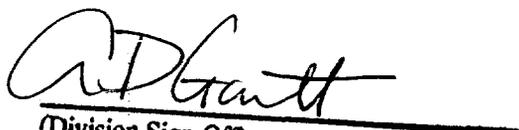
Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K982543

Device Name: **SilverSpeed™ Hydrophilic Guidewire**

Indications for Use: **The SilverSpeed 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.**



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

510(k) Number K982543

(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)