K053265

## II. Safety and Efficacy Summary

### A. *Contact Information*

Margaret Webber
Director, Regulatory and Clinical Affairs
Micrus Corporation
610 Palomar Avenue
Sunnyvale, CA 94085

APR 28 2005

### B. *Device Name*

Micrus Watusi 0.014" Guide Wire
Device: Wire, Guide, Catheter
Regulation Number: 870.1330
Product Code: DQX
Device Class: 2

### C. *Predicate Device(s)*

| Number | Description | Clearance Date |
|---|---|---|
| K971254 | Transend Ex Platinum 0.014 Guide Wire | July 1, 1997 |

### D. *Device Description*

The Micrus guide wire consists of these major components:

- A flexible proximal shaft.
- A distal, atraumatic, radiopaque, coiled tip.
- A tapered core wire.
- A hydrophilic coating covering the distal end.
- A detachable torque device (pin vise type).
- An insertion tool or shaping mandrel

### E. *Intended Use*

Micrus Watusi guide wire is intended for general intravascular use, including the neuro and peripheral vasculature. The guide wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. A torque device (pin vise) in included with the guide wire to facilitate directional manipulation of the guide wire. An introducer device is included to introduce the guide wire into the catheter or hemostatic valve, and can also be used to shape the flexible tip of the guide wire, as desired.

### F. *Intended Use Predicate Device (per products' Instructions for Use)*

Boston Scientific Target's Transend Ex family guide wires are intended for general intravascular use, including the neuro and peripheral vasculature. The guide wire can be torqued to facilitate the

selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries. A torque device (pin vise) is included with the guide wire to facilitate directional manipulation of the guide wire.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2006

Micrus Endovascular
c/o Ms. Margaret Webber
Director, Regulatory and Clinical Affairs
821 Fox Lane
San Jose, CA 95131

Re: K053265
Trade/Device Name: Micrus Watusi 0.014" Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: Class II
Product Code: DQX
Dated: April 14, 2006
Received: April 17, 2006

Dear Ms. Webber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchmes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K053265

Device Name: Micrus Guide Wire, Watusi 0.014

Indications For Use:

Micrus Watusi guide wire is intended for general intravascular use, including the neuro and peripheral vasculature. The Watusi guide wire is not intended for use in the coronary arteries. The guide wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. A torque device (pin vise) in included with the guide wire to facilitate directional manipulation of the guide wire. An introducer device is included to introduce the guide wire into the catheter or hemostatic valve, and can also be used to shape the flexible tip of the guide wire, as desired.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna P. Kochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K053265