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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)

1. The trade or proprietary name of the device is the Medtronic® MUSTANG™ Steerable Guide Wire. Models offered in this product line include:

   - Medtronic® MUSTANG™ Super Floppy Steerable Guide Wire
   - Medtronic® MUSTANG™ Floppy Steerable Guide Wire
   - Medtronic® MUSTANG™ Intermediate Steerable Guide Wire
   - Medtronic® MUSTANG™ Standard Steerable Guide Wire
   - Medtronic® MUSTANG™ Extra Support Steerable Guide Wire.

   The common or classification name is Coronary Guidewire.

2. The Medtronic® MUSTANG™ Steerable Guide Wire is for use in introducing and placing interventional catheters during percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

3. The Medtronic® MUSTANG™ Steerable Guide Wire is a guide wire having a maximum diameter of 0.014" (0.36 mm). The proximal shaft is coated with a polymer and the distal 33 cm contains a lubricious coating. The distal segment of the wire contains a spring which is radiopaque. The MUSTANG™ is provided sterile, and is intended for one procedure use only (disposable).

4. *In vitro* testing included tensile strength, torque strength, torqueability, tip flexibility, coating adherence/integrity and catheter compatibility. Testing was also performed to assess the biocompatibility of the device.

5. Test results verified that the MUSTANG™ meets all of the applicable specifications and is deemed adequate for the intended use. The MUSTANG™ line of guide wires is considered to be substantially equivalent to the following devices:

   - Medtronic® Mustang™ Steerable Guide Wire
   - ACS® Hi-Torque Floppy II® Guide Wire
   - ACS® Hi-Torque Intermediate® Guide Wire
   - ACS® Hi-Torque Standard® Guide Wire
   - ACS® Hi-Torque Extra S'port™ Guide Wire
   - SciMed® Sceptor™ Floppy Guide Wire

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1997

Ms. Mary De Armond
Medtronic Interventional Vascular
9410 Carroll Park Drive
San Diego, California 92121-2256

Re: K972944
Medtronic® MUSTANG™ Steerable Guide Wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: August 7, 1997
Received: August 11, 1997

Dear Ms. Armond:

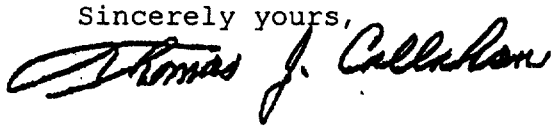
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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) 594-4639. 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, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA

Device Name: Medtronic® Mustang™ Steerable Guide Wire

Indications For Use: The Mustang™ Steerable Guide Wire is indicated for use in introducing and placing interventional catheters during percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tara A. Rupp

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972944

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)