K980973

DEC 10 1998

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® Angiographic Catheter. Models offered in this product line include Medtronic® 4F Angiographic Catheter, Medtronic® 5F Angiographic Catheter, Medtronic® 6F Angiographic Catheter and Medtronic® 7F Angiographic Catheter. The classification name is Diagnostic Intravascular Catheter.

2. The Medtronic® Angiographic Catheter is designed to be used for delivering radiopaque media and making pressure measurements in selected coronary sites within the vascular system.

3. The Medtronic® Angiographic Catheters are 4F, 5F, 6F and 7F in diameter with a braided proximal shaft, non-braided distal segment and a variety of tip configurations.

4. All appropriate biocompatibility tests were successfully performed on the materials used for the Medtronic® Angiographic Catheters.

5. Test results verified that the Medtronic® Angiographic Catheter meets all of the applicable specifications and is deemed adequate for the intended use. The line of angiographic catheters is considered to be substantially equivalent to the following devices:

    - Medtronic Cascade® Angiographic Catheter
    - USCI® Angiographic Catheter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 1998

Mr. Mark Chartier
Quality Assurance and Regualtory Affairs Manager
Medtronic Interventional Vascular, Inc.
37A Cherry Hill Drive
Danvers, MA 01923

Re: K980973
Trade Name: Medtronic® Angiographic Catheter
Regulatory Class: II
Product Code: DQO
Dated: September 11, 1998
Received: September 14, 1998

Dear Mr. Chartier:

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,

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

INDICATIONS FOR USE

510(k) Number: To be assigned by FDA

Device Name: Medtronic® Angiographic Catheter

Indications for Use: The Medtronic® Angiographic Catheter is designed to be used for delivering radiopaque media and making pressure measurements in selected coronary sites within the vascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Doug Gail for TJ Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980973

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)