AUG - 7 1998

K981198

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® Zuma™ Guiding Catheter. The Medtronic® Zuma™ Guiding Catheter will be available in the 6F size and in curve styles similar to the current Medtronic Guiding Catheters.
2. The Medtronic® Zuma™ Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.
3. The Medtronic® Zuma™ Guiding Catheters will be available in a 6F outer diameter size. The catheter is constructed with a braided proximal shaft with an inner liner and a soft distal tip. The inner lumen of the catheter has a thin lubricious coating. The Zuma™ Guiding Catheter has a larger inner lumen diameter and a stiffer shaft.
4. All appropriate Biocompatibility tests were successfully performed on the materials used for the Medtronic® Zuma™ Guiding Catheter.
5. Test results verified that the Medtronic® Zuma™ Guiding Catheters meets all of the applicable specifications and is deemed adequate for the intended use. The guide catheters is considered to be substantially equivalent to the following device:
    - Medtronic® Vector™ X Guiding Catheter
    - Cordis® Brite Tip® Guiding Catheter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 1998

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

Re: K981198/S1
Trade Name: Medtronic® 6F Zuma™ Guiding Catheter
Regulatory Class: II
Product Code: DQY
Dated: June 24, 1998
Received: June 25, 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 Health
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® Zuma™ Guiding Catheter

Indications for Use: The Medtronic® Zuma™ Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The Zuma catheter is intended to be used in the coronary or peripheral vascular system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K981198

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