

DEC 13 2004

Appendix 2. 510(k) Summary

Submitter: Medtronic Vascular
37A Cherry Hill Drive
Danvers, MA 01923
USA

Contact Person: Fred Boucher
Director, Regulatory Affairs
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Date Prepared: August 17, 2004

Trade Name: 6F Z4 Guiding Catheter

Common Name: Percutaneous Catheter

Classification Name: Percutaneous Catheter

Predicate Device: 6F Launcher Guide Catheter K021256

Device Description: The 6F Z4 Guide Catheter consists of a luer hub, a strain relief, inner liner, a braided wire, an outer jacket, a sleeve, a tungsten/nylon band, and a soft tip.

The 6F Z4 Guide Catheter design is based on an inner lumen liner of polyethylene material. The new shaft will be comprised of an inner liner of polyethylene, an intermediate layer of Pebax, stainless steel braid wire and a Vestamid outer jacket. The braided wire, intermediate layer and outer jacket materials have been previously used in others Medtronic Guide Catheters.

Statement of Intended Use: Provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system

Summary of Technological Characteristics: In addition to being technologically equivalent to the predicate devices, the 6F Z4 Guiding Catheter has been subjected to performance testing and it has been determined that the 6F Z4 Guiding Catheter is suitable for its intended

use.

Summary of Non-clinical Data:

The 6F Z4 Guiding Catheter is manufactured under the same conditions, using the similar processes and equivalent materials, as the 6F Launcher Guiding Catheter; the legally marketed predicate device. In addition to being technologically equivalent, the indications for use have not changed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2004

Medtronic Inc.
c/o Mr. Fred Boucher
Director, Regulatory Affairs
37A Cherry Hill Drive
Danvers, MA 01923

Re: K042489
Trade/Device Name: 6F Z4 Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 22, 2004
Received: November 23, 2004

Dear Mr. Boucher:

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 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

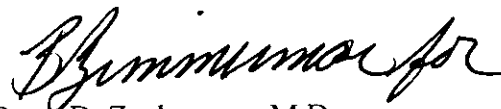
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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/dsma/dsmamain.html>

Sincerely yours,



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: K042489

Device Name: Medtronic 6F Sherpa NX Guiding Catheter

Indications for Use: The Medtronic 6F Sherpa NX Guide Catheter is designed to provide a pathway through which therapeutic devices are introduced. The Sherpa NX guiding catheter is intended for used in the coronary or peripheral vascular system.

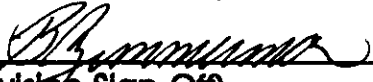
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(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 Devices
510(k) Number K042489

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