



**Medtronic**

SEP - 8 2006

K062420

Medtronic Vascular  
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Danvers, MA 01923  
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### 510(k) Summary

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

**Contact Person:** Mark Puopolo  
Sr. Regulatory Affairs Specialist  
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**Date Prepared:** August 16, 2006

**Trade Name:** 5F Sherpa® Active NX Guide Catheter

**Common Name:** Percutaneous Catheter

**Classification Name:** Percutaneous Catheter

**Predicate Device:** 8F Sherpa NX Guide Catheter (K060418)  
5F Launcher Guide Catheter (K030779)

**Device Description:**  
The 5F Sherpa Active NX Guiding Catheter consists of a luer hub, strain relief, a shaft (outer jacket, braid wire, an intermediate layer, and inner liner), a secondary segment, a primary segment, tungsten marker band, a segment sleeve and a soft tip.  
The 5F Sherpa Active NX Guide Catheter design is based on a four layer design with an inner liner of polyethylene.

**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

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**Summary of  
Technological  
Characteristics:**

In addition to being technologically equivalent to the predicate devices, the 5F Sherpa Active NX Guiding Catheter has been subjected to performance testing and it has been determined that the 5F Sherpa Active NX Guiding Catheter is suitable for its intended use.

**Summary of Non-  
clinical Data:**

The 5F Sherpa Active NX Guiding Catheter is manufactured under the same conditions, using the similar processes and equivalent materials, as the 8F Sherpa NX Guiding Catheter; and 5F Launcher Guiding Catheter, the legally marketed predicate devices. In addition to being technologically equivalent, the indications for use have not changed.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Medtronic, Inc  
c/o Mr. Mark Puopolo  
Sr. Regulatory Affairs Specialist  
37A Cherry Hill Drive  
Danvers, MA 01923

Re: K062420  
Medtronic® Vascular 5F Sherpa® Active NX Guide Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous catheter  
Regulatory Class: II  
Product Code: DQY  
Dated: August 16, 2006  
Received: August 18, 2006

Dear Mr. Puopolo:

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.

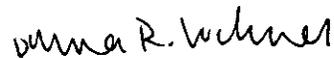
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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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 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.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 (if known): K062420

Device Name: Medtronic® 5F Sherpa Active NX Guiding Catheter

Indications For Use: The Medtronic 5F Sherpa Active NX Guidé Catheter is designed to provide a pathway through which therapeutic devices are introduced. The 5F Sherpa Active NX Guiding Catheter is intended for use 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Diana R. Valmer  
(Division Sign-Off)  
Division of Cardiovascular Devices

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