K051846

AUG 5 - 2005

510(k) Summary

Submitter:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923 USA
Contact Person:	Fred Boucher Director, Regulatory Affairs 978.739.3116 978.777.0390 Fred.Boucher@Medtronic.com
Date Prepared:	July ~~XX~~ 06, 2005
Trade Name:	7F Sherpa NX Guiding Catheter
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter
Predicate Device:	6F Sherpa NX Guide Catheter (K042489)
Device Description:	The 7F Sherpa NX guide catheter consists of a luer hub, strain relief, a shaft (outer jacket, braid wire, an intermediate layer, and inner liner), a secondary (transition) segment, a primary segment, tungsten marker band, a segment sleeve and a soft tip. The 7F Sherpa NX Guide Catheter design is based on a four layer design with an inner linner 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
Summary of Technological	In addition to being technologically equivalent to the predicate devices, the 7F Sherpa NX Guiding Catheter has

Characteristics:	been subjected to performance testing and it has been determined that the 7F Sherpa NX Guiding Catheter is suitable for its intended use.
Summary of Non-clinical Data:	The 7F Sherpa NX Guiding Catheter is manufactured under the same conditions, using the similar processes and equivalent materials, as the 6F Sherpa NX 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

AUG 5 - 2005

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

Re: K051846
Medtronic® 7F Sherpa NX Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: July 6, 2005
Received: July 7, 2005

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 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/industry/support/index.html.

Sincerely yours,

Donna R. Lechner

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): K051846

Device Name: Device name: Medtronic® 7F Sherpa NX guiding Catheter

Indications For Use: The Medtronic 7F Sherpa NX Guide Catheter is designed to provide a pathway through which therapeutic devices are introduced. The 7F 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)

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051846