K030671

JUL 3 1 2003

VI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(Pursuant to Section 12, Safe Medical Devices Act of 1990)

A. Submitter Information:

Name:	Medtronic, Inc.
Address:	37A Cherry Hill Drive, Danvers, MA 01923
Phone:	978-777-0042
Fax:	978-777-0390
Contact Person:	Fred Boucher, Regulatory Affairs Manager
Date of Preparation:	February 28, 2003

B. Device Name:

Trade Name:	Medtronic® 7F and 8F Launcher Biopsy Guide Catheter
Common Name:	Guide Catheter
Classification Name:	Intravascular Catheter / Percutaneous Catheter

C. Predicate Device Names Medtronic® 7F and 8F Launcher Guide Catheters
Medtronic SHERPA II (Vector)Guide Catheters

D. Device Description: Medtronic® 7F and 8F Launcher Biopsy Guide Catheter

E. Intended Use The Medtronic 7F and 8F Launcher Biopsy guide Catheters provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used to for the percutaneous introduction of biopsy devices.

F. Technological Characteristics Summary

1. The Medtronic 7F and 8F Launcher Biopsy Guide Catheters are identical to the Medtronic 7F and 8F Launcher Guide Catheters regarding materials, components, design, packaging and sterilization.

2. The indications for use are identical to the Medtronic SHERPA II (commercialized as Vector) regarding the percutaneous introduction of biopsy forceps and the Medtronic Launcher Guide Catheters regarding coronary and peripheral access. They are all indicated to provide a pathway through which therapeutic devices are introduced. The Medtronic Launcher Biopsy Guide Catheter indications for use are as follows:

Medtronic Launcher Biopsy Guide Catheter is designed to provide a pathway through which therapeutic devices are introduced. This includes the introduction of biopsy forcep devices. The guiding catheter is intended to be used in accessing the coronary or peripheral system.

3. Similar to the Medtronic Launcher Guide Catheters the Medtronic Launcher Biopsy Catheters will be available in 7F and 8F sizes. Similar to the Medtronic SHERPA II (Vector) Biopsy Guide Catheters, the Medtronic Launcher Biopsy Catheters will be available in one specific curve style.

4. The Medtronic® Launcher Biopsy Guide Catheters are constructed with a braided proximal shaft with an inner liner a secondary segment (8F only), primary segment, a sleeve and a soft distal tip. The inner lumen of the catheter has a thin lubricious coating.

5. All appropriate biocompatibility tests were successfully performed on the materials used for the Medtronic Launcher Biopsy Guide Catheter.

6. Results of testing verified that the Medtronic Launcher Biopsy Guide Catheters meet all applicable standards and specifications and are deemed adequate for the intended use. The guide catheters are considered to be substantially equivalent to the following device:

    - 7F Launcher Guide Catheter (K022764)
    - 8F Launcher Guide Catheter (K023402)
    - SHERPA, SHERPA II (commercialized as Vector) and ASCENT biopsy Guide Catheters (K944668)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 1 2003

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

Re: K030671
Medtronic® 7F and 8F Launcher Biopsy Guide Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 17, 2003
Received: June 18, 2003

Dear Mr. Boucher:

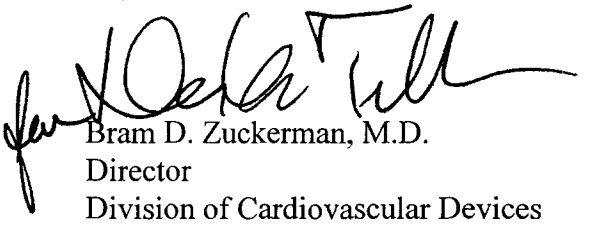
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (301) 594-4646. 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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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

Attachment 2
K030671

D. Indications For Use

Device Name: Medtronic 7F and 8F Launcher Right Ventricular Biopsy Guide Catheters

Indications for Use: The Medtronic 7F and 8F Launcher Right Ventricular Biopsy Guiding Catheters are intended to be used for the percutaneous introduction of biopsy forceps into the right ventricle of the heart.

Contraindications: None

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K030671

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)