FEB 2 8 2002

K013963

510(K) SUMMARY

Date Prepared:	October 19, 2001
Submitter:	Medtronic, Inc. 7000 Central Ave. N.E. Minneapolis, MN 55432
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Trade / Proprietary Name:	Medtronic Model 9210 Delivery Catheter
Common Name:	Catheter, Percutaneous
Device Classification:	Class II, 21 CFR 870.1250
Product Code:	74 DQY

Device Description

The Medtronic Model 9210 delivery catheter is designed to provide a pathway through which Medtronic transvenous devices, such as leads or catheters, are introduced into the venous vessels and chambers of the heart.

The delivery catheter features two lumens. The large lumen is used for passing Medtronic leads or other Medtronic transvenous devices. The small lumen is designed to accept a stylet; the stylet facilitates passage and placement of the delivery catheter. The proximal opening of the small lumen features a stylet guide on the proximal end of the delivery catheter. This delivery catheter is intended for temporary use (contemplated implant duration of eight hours or less).

The catheter will be introduced into the patient via standard cut down or percutaneous technique, maneuvered through the vasculature using a stylet in the small lumen and appropriately positioned in the heart for the introduction of devices through the larger lumen.

Indications for Use

The Medtronic Model 9210 Delivery Catheter is intended for device passage and placement within the venous vessels and chambers of the heart. .

Substantially Equivalent Device

The Medtronic Model 9210 catheter is substantially equivalent to the Medtronic Vector/Vector X Guide Catheter submitted under the name Medtronic GCIII Coronary Guiding Catheter (K950179, cleared 7/25/95).

The Model 9210 Delivery Catheter contains two lumens; the Vector/Vector X contains one lumen. The large lumen of the Model 9210 is used for passing Medtronic leads or other Medtronic transvenous devices. The small lumen is designed to accept a stylet and is lined with an MP35N coil. The stylet adds stiffness to the catheter and allows it to be steered through the vasculature. The Vector/VectorX catheter is also steerable; however, the shaft of the Vector/Vector X catheter contains stainless steel braid to increase the stiffness of the catheter, allowing it to be steered through the vasculature. The use of stylets to introduce pacemaker and internal defibrillator leads through the vasculature has been proven to be safe and effective. These products have been legally marketed for a number of years. Many of these leads contain a lumen lined with an MP35N coil through which the stylets are guided. Therefore, no additional risks are presented due to this design feature.

The main body of the Model 9210 and GC III (Vector/Vector X) catheters are both composed of Pebax. Acrylamide is polymerized onto the surface of the main lumen of the Model 9210 catheter whereas the inner lumen of the Vector/Vector X is coated with MDX4-4159. Functionally, the hubs of both catheter designs allow for mating of standard Luer fittings, although the material of the hubs is different. The materials for both catheters have been fully tested for biocompatibility; therefore, any potential risks due to biocompatibility have been mitigated. The functionality of the Model 9210 catheter for use with typical Medtronic leads has been demonstrated thorough bench testing.

The differences in design between the Model 9210 and the Vector/Vector X are fully described in this submission and do not require comparative testing. Performance and biocompatibility testing for the Model 9210 Delivery Catheter is described in this submission. Qualification testing was performed to assure the Model 9210 Delivery Catheter conforms to design specification and reliability intent.

Summary of Studies

The following tests were performed to assure the Model 9210 Delivery Catheter conform to design specification and reliability intent: dry stylet perforation, dry stylet bottoming, catheter compatibility, composite torsional strength, and composite tensile strength.

The Model 9210 Delivery Catheter tissue contacting materials were tested according to FDA Blue Book Memorandum #G95-1, and ISO Standard 10993-1, Biological Evaluation of Medical Devices Part 1: Guidances and Selection of Tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Mary Ellen Best
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K013963
Model 9210 Guiding Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: November 30, 2001
Received: December 3, 2001

Dear Ms. Best:

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 and additionally 21 CFR Part 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 Part 807.97). 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 Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): N/A K013963

Device Name: Model 9210 Guiding Catheter

Indications For Use: The Medtronic Model 9210 Delivery Catheter is intended for device passage and placement within the venous vessels and chambers of the heart.

Contraindications: The delivery catheter is contraindicated for patients with sepsis or a hypercoagulable state.

The delivery catheter is contraindicated for right ventricular use in patients with tricuspid valvular disease or a mechanical tricuspid heart valve.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013963

Medtronic