510(K) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Date Prepared:	22 December 2003
Submitter:	Medtronic Inc. 7000 Central Avenue NE Minneapolis, MN 55432
Contact:	Kristy K. Mollner, MS, RAC Sr. Regulatory Affairs Specialist
Telephone:	(763) 514-4189
Fax:	(763) 514-6424
Email:	kristina.mollner@medtronic.com
Proprietary Name	Medtronic® SelectSite™ Model C304-S59 Deflectable Catheter System Medtronic® SelectSite™ Model C304-L69 Deflectable Catheter System
Common Name:	Catheter, Percutaneous
Device Classification:	Class II, 21 CFR § 870.1250
Product Code:	74 DQY

Device Description

The Medtronic SelectSite Model C304 Deflectable Catheter System is designed to facilitate the introduction of transvenous devices within the chambers and coronary vasculature of the heart and the introduction of leads in the left heart via the coronary sinus.

The Model C304-S59 deflectable catheter has a single lumen for passage of transvenous devices with a maximum outer diameter of 5.6 French (1.9 mm) and a usable length of 30 cm.

The Model C304-L69 deflectable catheter has a single lumen for passage of transvenous devices with a maximum outer diameter of 5.6 French (1.9 mm) and a usable length of 40 cm.

The deflectable catheter features a deflecting distal section controlled by the deflectable catheter handle for placement of transvenous devices within the chambers of the heart and for coronary sinus cannulation. The body of the deflectable catheter is radiopaque for visibility on fluoroscopy.

Indications for Use

The deflectable catheter system is indicated to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart, and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

Substantially Equivalent Devices

Predicate Device	Manufacturer	510(k) Number
Medtronic 10600 Deflectable Catheter Delivery System	Medtronic	K013517
Medtronic Attain Model 6226DEF Deflectable Catheter System	Medtronic	K032312
Introducer Valve Model 6228VAL	Cook Vascular Incorporated	K010128
Universal Slitter Model 6228SLT	Medtronic	Class 1 device exempt from pre-market notification

Summary of Studies

InVitro testing was performed to support substantial equivalence to the predicate device(s). The SelectSite Model C304 Deflectable Catheter System met all specified design and performance requirements.

Biocompatibility Information

All device materials / components were assessed for biocompatibility consistent with ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing". All materials were found to be biocompatible and in compliance to ISO 10993-1.

Sterilization Validation

The SelectSite Model C304 Deflectable Catheter System will be sterilized using a validated 100% Ethylene Oxide (EtO) sterilization process.

Conclusion

Through the data and information presented, as well as similarities to legally marketed devices, Medtronic, Inc. considers the SelectSite Model C304-S59 and C304-L69 Deflectable Catheter Systems to be substantially equivalent to legally marketed predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2004

Medtronic, Inc
c/o Ms. Kristy K. Mollner, M.S., RAC
Senior Regulatory Affairs Specialist
7000 Central Avenue NE Mail Stop CW304
Minneapolis, MN 55432-3576

Re: K033989
Trade Name: Medtronic® SelectSite™ Model C304-S59 Deflectable Catheter System and Medtronic® SelectSite™ Model C304-L69 Deflectable Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: December 22, 2003
Received: December 23, 2003

Dear Ms. Mollner:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

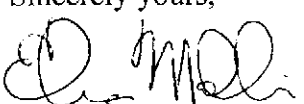
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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

INDICATIONS FOR USE

510(k) Number (if known): K033989

Device Name: Medtronic® SelectSite™ Model C304-S59 Deflectable Catheter System

Medtronic® SelectSite™ Model C304-L69 Deflectable Catheter System

Indications for Use: The deflectable catheter system is indicated to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart, and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Cardiovascular Devices

(Optional Format 1-2-96)

510(k) Number K033989