Medtronic

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE K061416

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Date Prepared:	May 19, 2006
Applicant:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Submission Correspondent:	Michelle Nivala Regulatory Affairs Specialist Medtronic, Inc. 1015 Gramsie Road Shoreview MN 55126-3082 USA
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Proprietary Name:	SelectSite™ C304 Deflectable Catheter System
Common Name:	Catheter, Percutaneous
Device Classification:	Class II, 21 CFR 870.1250
Product Code:	DQY

OCT 25 2006

Device Description

The SelectSite™ C304 Deflectable Catheter System contains 1 deflectable catheter, 1 deflectable catheter dilator, 1 universal slitter, 1 valve, 1 guidewire, 1 needle and 1 syringe. The SelectSite™ C304 Deflectable Catheter System is designed to access the coronary sinus and the chambers of the heart. The percutaneous needle and syringe are used to access the venous insertion site, the guidewire to access the vein, the introducer valve to reduce blood loss during the implant procedure, the deflectable catheter to introduce a transvenous device, the deflectable catheter dilator to facilitate deflectable catheter passage and the guide catheter slitter to remove the deflectable catheter. The SelectSite™ C304 Deflectable Catheter System is available in four models which are the

C304-S59, C304-L69, C304-XS59 and C304-XL74. All components except the deflectable catheter and dilator are identical in each model.

Indications for Use
The deflectable catheter system is indicated to provide a pathway though 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:
The SelectSite™ C304 Deflectable Catheter System uses similar technology and has similar intended uses, function, materials and method of operation to the following predicate devices:

- SelectSite™ C304-S5901 and C304-L6901 Deflectable Catheter Systems (K#033989, cleared January 22, 2004)
- Medtronic Attain® 6226DEF Deflectable Catheter Delivery System (K#032312, cleared November 3, 2003)

Summary of Studies:
Device integrity testing was performed to support the equivalency of the SelectSite™ C304 Deflectable Catheter System to the predicate devices. Testing included mechanical, functional, and biocompatibility testing. The SelectSite met all specified design and performance requirements.

Biocompatibility Information
The biocompatibility evaluation completed for the SelectSite™ C304 Deflectable Catheter Delivery System verifies that the SelectSite™ C304 Deflectable Catheter System is biocompatible. The testing which supports the biocompatibility of the SelectSite™ C304 Deflectable Catheter System is consistent with International Standard ISO 10993-1:, "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing." When classified according to this standard, the catheter and dilator included in the SelectSite™ C304 Deflectable Catheter System are external communicating devices with limited exposure (<24 hours) to circulating blood.

Sterilization Validation
The SelectSite™ C304 Deflectable Catheter System will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion
Through the data and information presented, Medtronic Ireland considers the SelectSite™ C304 Deflectable Catheter System to be substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 25 2006

Medtronic Ireland
c/o Ms. Michele Nivala
Regulatory Affairs Specialist
Medtronic, Inc.
1015 Gramsie Road
Shoreview, MN, 55126-3082

Re: K061416
Trade/Device Name: Selectsite C304 Deflectable Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 4, 2006
Received: October 10, 2006

Dear Ms. Nivala:

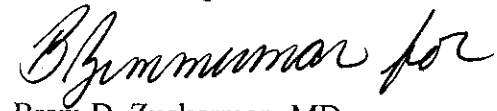
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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-__. 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,



Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K061416

Device Name: SelectSite C304 Deflectable Catheter System

Indications For Use: The deflectable catheter system is indicated to provide a pathway though 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.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061416