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**510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE**

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Date Prepared: August 11, 2004

Submitter: Medtronic Ireland  
Parkmore Business Park West  
Galway  
Ireland

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Proprietary Name: Attain Select™ 6238TEL Guide Catheter Set for  
Left-heart Delivery

Common Name: Catheter, Percutaneous

Device Classification: Class II, 21 CFR 870.1250

Product Code: DQY

**Device Description**

The Attain Select 6238TEL Guide catheter set for left-heart delivery consists of a set of 3 catheters, one straight catheter; one catheter with a 90° curved tip and one catheter with a 180° curved tip. The Attain Select 6238TEL guide catheters are designed to facilitate access to the coronary sinus and left-heart venotomy. The catheters provide a pathway for the delivery of contrast medium and transvenous devices such as guide wires and guide catheters. The Attain Select 6238TEL guide catheters are provided sterile and are intended for single use only.

The catheters, which have a working length of 70cm, also have radiopaque, flexible tips. The catheter functions as an inner catheter and, when used with an outer guide catheter, forms a dual-catheter assembly. The Attain Select 6238TEL guide catheters feature a lumen that allows for the passage of guide wires up to 0.89 mm (0.035 in) in diameter. The guide catheters have a maximum outer diameter of 7 French (2.4 mm) and may be

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Medtronic Ireland  
Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery  
Traditional 510(k)

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used with delivery systems that accept a 7 French (2.4 mm) transvenous device. Medtronic recommends using the guide catheters with Medtronic Attain Fixed Shape catheters or the Medtronic Attain Deflectable catheter.

**Indications for Use**

The Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery is intended for the delivery of contrast media and transvenous devices to the coronary sinus and left heart venotomy. The 6238TEL guide catheters are indicated for use with an outer guide catheter delivery system, forming a dual-catheter assembly.

**Substantially Equivalent Devices:**

The Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery uses similar technology and has similar intended uses, function, materials and method of operation to the following predicate devices:

- Medtronic Attain™ Access 6218A Left-Heart Delivery System (K#021589, cleared May 30, 2002)
- Attain™ Prevail® Steerable Catheter Set, Model 6228CTH (K031211, cleared July 17, 2003)
- Guidant RAPIDO™ Guiding Catheter (K#021455, cleared August 2, 2002)

**Summary of Studies:**

Device integrity testing was performed to support the equivalency of the Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery to the predicate devices. Testing included mechanical, functional, and biocompatibility testing. The Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery met all specified design and performance requirements.

**Biocompatibility Information**

Medtronic has tested the materials used to fabricate the Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery for biocompatibility. The testing performed by Medtronic is consistent with International Standard ISO 10993-1: 2003, "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing." When classified according to this standard, the devices included in the Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery are external communicating devices with limited exposure (<24 hours) to circulating blood.

**Sterilization Validation**

The Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

**Conclusion**

Through the data and information presented, Medtronic Ireland considers the Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery to be substantially equivalent to legally marketed predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 15 2004

Medtronic, Inc.  
c/o Ms. Lynn Jensen  
Sr. Regulatory Affairs Specialist  
Parkmore Business Park West  
Galway  
IRELAND

Re: K042194  
Medtronic Attain Select™ 6238 TEL Guide Catheter Set for Left-Heart Delivery:  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: II (two)  
Product Code: DQY  
Dated: August 11, 2004  
Received: August 12, 2004

Dear Ms. Jensen:

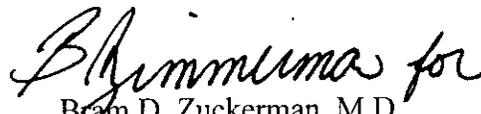
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) 594-4648. 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/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

**INDICATIONS FOR USE**

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510(k) Number (if known): K042194

**Device Name:** Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery

**Indications For Use:** The Attain Select™ 6238TEL Guide Catheter Set for Left-Heart Delivery is intended for the delivery of contrast media and transvenous devices to the coronary sinus and left heart venotomy. The 6238TEL guide catheters are indicated for use with an outer guide catheter delivery system, forming a dual-catheter assembly.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

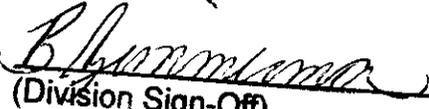
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K042194