K042194
p1/2

SEP 1 5 2004

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Date Prepared:	August 11, 2004
Submitter:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Contact:	Lynn Jensen Sr. Regulatory Affairs Specialist
Telephone:	(763) 514 4459
Fax:	(763) 514 6424
E-Mail	lynn.a.jensen@medtronic.com
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

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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,

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

Enclosure

INDICATIONS FOR USE

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 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 K042194