Medtronic K080428

DEC 0 9 2008

## 510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

**Date Prepared:** February 14, 2008

**Applicant:**
Medtronic Ireland
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Galway
Ireland

**Submission Correspondent:**
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**Proprietary Name:** Attain Command™ 6250 Left Heart Delivery Systems

Attain Command™ 6250 Guide Catheters for Left Heart Delivery

**Common Name:** Catheter, Percutaneous

**Device Classification:** Class II, 21 CFR 870.1250

**Product Code:** DQY

**Device Description:**

The **Attain Command™ Left Heart Delivery Systems** contain two guide catheters, one guide catheter dilator, one guide wire, one valve and one slitter. It is designed to access the coronary sinus and the chambers of the heart using the guidewire to access the vein, the valve to reduce blood loss during the implant procedure, the guide catheter to introduce a transvenous device, the guide catheter dilator to facilitate catheter passage and the slitter to remove the guide catheter.

The Attain Command™ Left Heart Delivery Systems are available in *two models:*

- Attain Command™ 6250C Left Heart Delivery System
- Attain Command™ 6250S Left Heart Delivery System.

All components with the exception of the two guide catheters are identical in both models. The guide catheters are different in each model with respect to the guide catheter shape and length.

The **Attain Command™ Guide Catheters for Left Heart Delivery** are individual packs, each containing one guide catheter and one guide catheter dilator. It is also designed to access the coronary sinus and the chambers of the heart using the

guide catheter to introduce a transvenous device and the guide catheter dilator to facilitate catheter passage.

The Attain Command™ Guide Catheters for Left Heart Delivery are available in *eleven models* as follows:

- Attain Command™ 6250-45S Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-50S Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-57S Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-AM Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-EH Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-EHXL Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-MB2 Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-MB2X Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-MP Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-MPR Guide Catheter for Left Heart Delivery
- Attain Command™ 6250-MPX Guide Catheter for Left Heart Delivery

Each model is different with respect to the guide catheter shape and length and the dilator length

**Indications For Use:**

The Attain Command™ 6250 Left Heart Delivery Systems and the Medtronic Attain Command™ 6250 Guide Catheters for Left Heart Delivery are intended for introducing transvenous devices and leads into vessels of the left heart via the coronary sinus

**Substantially Equivalent Devices:**

Attain Command™ 6250 Left Heart Delivery Systems and the Attain Command™ 6250 Guide Catheters for Left Heart Delivery uses similar technology and has similar intended uses, function, materials and method of operation to the following predicate devices:

- Attain Select™ II 6248DEL Delivery Catheter System (510(k) K053431).
- Attain™ Access 6218A Left Heart Delivery System (510(k) K021589). Also commercialized under this 510(k) number is the Attain™ 6218A-45S, 6218A-50S, 6218A-57S and 6218A-EH Guide Catheters for Left-Heart Delivery individual packs.
- Attain™ LDS 6216A Left Heart Delivery System (510(k) K021587). Also commercialized under this 510(k) number is the Attain™ 6216A-MB2 Guide Catheter for Left-Heart Delivery.
- Attain™ 6218A-AM Guide Catheter for Left-Heart Delivery (510(k) K024035). Also commercialized under this 510(k) number is the Attain™ 6218A-EH Guide Catheter for Left-Heart Delivery individual pack.
- Attain™ 6218A-MP Guide Catheter for Left-Heart Delivery (510(k) K024032)

**Medtronic**

**Summary of Studies:**

Device integrity testing was performed to support the equivalency of the Attain Command™ product family to the predicate devices. Testing included mechanical, functional, and biocompatibility testing. The Attain Command™ product family met all specified design and performance requirements.

**Biocompatibility Information:**

The biocompatibility evaluation completed for the Attain Command™ product family verifies that the Attain Command™ Left Heart Delivery Systems and the Attain Command™ Guide Catheters for Left Heart Delivery are biocompatible.

The testing which supports the biocompatibility of the Attain Command™ Left Heart Delivery Systems and the Attain Command™ Guide Catheters for Left Heart Delivery is consistent with International Standard ISO10993-1:2003, "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing."

When classified according to this standard, the catheter and dilator included in the Attain Command™ product family are categorized as external communicating devices with limited exposure i.e. whose contact with circulating blood is (less than) < 24 hours

**Sterilization Validation:**

The Attain Command™ Left Heart Delivery Systems and the Attain Command™ Guide Catheters 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 Command™ Left Heart Delivery Systems and the Attain Command™ Guide Catheters 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

DEC -9 2008

Medtronic, Inc.
c/o Ms. Marlene Peterson
8200 Coral Street NE
Mounds View, MN 55112

Re: K080428
Medtronic Attain Command™ 6250 Left Heart Delivery Systems;
Medtronic Attain Command ™ 6250 Guide Catheters for Left Heart Delivery
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: November 27, 2008
Received: December 01, 2008

Dear Ms. Peterson:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

## INDICATION FOR USE

510(k) Number (if known): K080428

**Device Name:** Attain Command™ 6250 Left Heart Delivery Systems and Attain Command™ 6250 Guide Catheters for Left Heart Delivery

**Indications For Use:** The Medtronic Attain Command™ 6250 Left Heart Delivery Systems and the Medtronic Attain Command™ 6250 Guide Catheters for Left Heart Delivery are intended for introducing transvenous devices and 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 K080428