510(K) SUMMARY

K063210

MAR 15 2007

Date Prepared:	October 20, 2006
Submitter:	Medtronic, Inc. Cardiac Rhythm Disease Management 7000 Central Avenue NE Minneapolis, MN 55432
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Proprietary Name:	Attain Hybrid Guide Wire
Common Name:	Catheter guide wire
Device Classification:	Class II, 21 CFR 870.1330
Product Code:	DQX

Summary of Substantial Equivalence

The intended use, design, materials and performance of the Attain Hybrid Guide Wires are substantially equivalent to the following predicate devices:

- Guidant HI-TORQUE WHISPER – Guide Wires with Hydrocoat Hydrophilic Coating (Models 6726, 6737, 6738, 4482, 4483, 4581, 4586, 4583, and 4588) – K030019 cleared January 24, 2003.
- Medtronic Stylet Kit Models 6254, 6282 and 6293 – K010906 cleared April 5, 2001
- Medtronic GT-1 Guide Wires (Floppy, Hi-Per Flex and Light Support) – K983927 cleared March 11, 1999
- Medtronic Silk Guide Wires – K903923 cleared November 21, 1990

Device Description

The Attain Hybrid Guide Wire is a single use guide wire designed to aid in the placement of Medtronic transvenous left ventricular leads in the coronary vasculature. The guide wires consist of a core wire with springs, and coatings. Near the distal end of the device, the core wire consists of tapers to allow differing support or stiffness levels.

Indications for Use

The Attain Hybrid Guide Wire is intended to aid in the placement of Medtronic transvenous left ventricular leads in the coronary vasculature.

Technological Characteristics

Intended use, design, materials, performance and packaging materials are substantially equivalent to the predicate devices referenced.

Summary of Testing

Device verification testing was performed to demonstrate the Attain Hybrid Guide Wires meet established performance criteria and to support equivalency to the referenced predicate devices. Visual, performance and compatibility testing was completed. All design and compatibility requirements were met.

Biocompatibility testing consistent with ISO 10993-1: 2003: "Biological Evaluation of Medical devices – Part 1: Evaluation and Testing" was also conducted.

The Attain Hybrid Guide Wire will be sterilized using a validated EtO sterilization process.

Conclusion

Medtronic considers the Attain Hybrid Guide Wires to be substantially equivalent to legally marketed predicate devices through the data and information presented. No safety or effectiveness issues were identified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAR 15 2007

Re: K063210
Trade/Device Name: Attain Hybrid Guide Wires Models GWR419378, GWR419388
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 5, 2007
Received: March 8, 2007

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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bochner

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): K063210

Device Name: Attain Hybrid Guide Wire

Indications for Use: The Attain Hybrid guide wire is intended to aid in the placement of Medtronic transvenous left ventricular leads in the coronary vasculature.

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)

Donna R. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

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