K082670

Medtronic

DEC 0 4 2008

510(k) SUMMARY OF SUBSTANTIAL EQUIVALENCE

Date Prepared:	September 12, 2008
Applicant:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Submission Correspondent:	Beth Claas Senior Regulatory Affairs Specialist Medtronic, Inc. 8200 Coral Sea Street MS MVS11 Mounds View MN 55112 USA
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E-Mail:	beth.a.claas@medtronic.com
Proprietary Name:	Attain Prevail™ 6228CTH80 Steerable Catheter Set
Common Name:	Catheter, Percutaneous
Device Classification:	Class II, 21 CFR 870.1250
Product Code:	DQY
Device Description:	The Attain Prevail™ 6228CTH80 Steerable Catheter Set contains one 80cm Steerable catheter, one guidewire, one Y-connector with valve, one extension set, 3-way stopcock, one guidewire clip and two guidewire torque tools.
Indications For Use:	The steerable catheter set is indicated to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.
Substantially Equivalent Devices:	The Attain Prevail™ 6228CTH80 Steerable Catheter Set uses similar technology and has similar intended uses, function, materials and method of operation to the following predicate devices: - Attain Prevail™ 6228CTH Steerable Catheter Set (510(k) K031211). Also commercialized under this 510(k) number is the current Attain Prevail™ 6228CTH80 Steerable Catheter Set. - Attain Prevail™ 6228SYS Left-Heart Delivery System, 80 cm Prevail catheter (510(k) K032622).
Summary of Studies:	Device integrity testing was performed to support the equivalency of the Attain Prevail™ 6228CTH80 Steerable Catheter Set to the predicate devices. Testing included bench, sterilisation and biocompatibility testing. The Attain Prevail™ 6228CTH80 Steerable Catheter Set met all specified design and performance requirements.

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Biocompatibility Information:	The biocompatibility evaluation completed for the Attain Prevail™ 6228CTH80 Steerable Catheter Set verifies that this device is biocompatible. The testing which supports the biocompatibility of the Attain Prevail™ 6228CTH80 Steerable Catheter Set is consistent with International Standard ISO10993-1:2003, "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing." When classified according to this standard, this device is categorized as external communicating devices with limited exposure i.e. whose contact with circulating blood is (less than) < 24 hours
Sterilization Validation:	The Attain Prevail™ 6228CTH80 Steerable Catheter Set will continue to be sterilized using a validated Ethylene Oxide (EtO) sterilization process.
Conclusion:	Through the data and information presented, Medtronic Ireland considers the Attain Prevail™ 6228CTH80 Steerable Catheter Set 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

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Medtronic, Inc.
c/o Ms. Beth Claas
Senior Regulatory Affairs Specialist
8200 Coral Sea Street MS MVS11
Mounds View, MN 55112

Re: K082670
Trade/Device Name: Attain Prevail™ 6228CTH80 Steerable Catheter Set
Common Name: Catheter, Percutaneous
Regulation Number: 21 CFR 870.1250
Regulatory Class: II
Product Code: DQY
Dated: November 5, 2008
Received: November 7, 2008

Dear Ms. Claas:

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,

Donna R. Lachman

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): K082670

Device Name: Attain Prevail™ 6228CTH80 Steerable Catheter Set

Indications For Use: The steerable catheter set is indicated to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

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. Vochner
(Division Sign-Off)
Division of Cardiovascular Devices

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