K112917

OCT 27 2011

4.0 510(k) Summary

Date Prepared:	September 29th, 2011
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Proprietary Name:	Attain LDS 6216A Left Heart Delivery System Attain Access 6218A Left Heart Delivery System Attain 6216A and 6218A Guide Catheters for Left Heart Delivery

Common Name:	Attain 6216A Left Heart Delivery System Attain 6218A Left Heart Delivery System Attain 6216A and 6218A Guide Catheters for Left Heart Delivery
Device Classification Name:	Catheter, Percutaneous Class II, 21 CFR 870.1250
Product Code:	DQY
Device Description:	The modified Attain 6216A and 6218A Left Heart Delivery Systems contain one or two guide catheters, one guide catheter dilator, one guidewire, one valve and one slitter. They are 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 modified Attain 6216A and 6218A Left Heart Delivery Systems are available in two models: • Attain LDS 6216A Left Heart Delivery System • Attain Access 6218A Left Heart Delivery System All components with the exception of the guide catheter (shape, length and quantity) and dilator (length) are identical in both models. The modified Attain 6216A/6218A Guide Catheters for Left Heart Delivery are individual packs, each containing one guide catheter and one guide catheter dilator. They are 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 modified Attain 6216A and 6218A Guide Catheters are available in seven models as follows: • Attain 6216A-MB2 Guide Catheter for Left Heart Delivery • Attain 6216A-MP Guide Catheter for Left Heart Delivery

	• Attain 6218A-AM Guide Catheter for Left Heart Delivery • Attain 6218A-45S Guide Catheter for Left Heart Delivery • Attain 6218A-EH Guide Catheter for Left Heart Delivery • Attain 6218A-50S Guide Catheter for Left Heart Delivery • Attain 6218A-57S Guide Catheter for Left Heart Delivery Each model is different with respect to guide catheter shape and length and the dilator length.
Indications For Use:	The modified Attain 6216A/6218A Product Family is intended for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.
Substantially Equivalent Devices:	The modified Attain 6216A/6218A Product Family uses similar technology and has similar intended uses, function, materials and method of operation to the following predicate devices: • 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 6216A-MP Guide Catheter for Left-Heart Delivery (510(k) K024032) • Attain Command 6250 Left Heart Delivery Systems and Guide Catheters for Left Heart Delivery (510(k) K090659).

Summary of Technological Characteristics:	The modified Attain 6216A and 6218A guide catheters for left heart delivery consist of an inner liner, and an outer jacket, with a wire braid encapsulated between the inner liner and outer layers. The distal tip is radiopaque to facilitate imaging under fluoroscopy and the hub at the proximal end of the shaft allows interfacing of the catheter with other devices used during the procedure. The catheter is packaged with a dilator. Additionally, the Attain 6216A and 6218A left heart delivery systems contain a valve to reduce blood loss and slitters to remove the guide catheter. The technological characteristics of the modified Attain 6216A and 6218A Product Family are identical to the predicate Attain 6216A and 6218A Product Family (510(k) K024032, K024035, K021587 and K021589) and the Attain Command Product Family (K090659).
Summary of Studies:	The modified Attain 6216A and 6218A Product Family met all specified design and performance requirements.
Summary of Clinical Data:	No clinical investigation has been performed for this device.
Biocompatibility Information:	The biocompatibility evaluation completed verifies that the modified Attain 6216A/6218A Left Heart Delivery Systems and the modified Attain 6216A/6218A Guide Catheters for Left Heart Delivery are biocompatible. The testing which supports the biocompatibility of the modified Attain 6216A/6218A Product Family 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 modified Attain 6216A/6218A Product Family are categorized as external communicating devices with limited exposure i.e. whose contact with circulating blood is (less than) < 24hours.
Sterilization Validation:	The modified Attain 6216A and 6218A Product Family will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.
Conclusion:	Through the data and information presented, Medtronic Ireland considers the modified Attain 6216A and 6218A Product Family to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

Medtronic, Inc.
c/o Ms. Deborah Kidder
Regulatory Affairs Specialist
8200 Coral Sea Street
Mounds View, MN 55112

Re: K112917
Trade/Device Name: Attain Catheter Product Family models 6216A and 6218A
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: September 30, 2011
Received: October 3, 2011.

Dear Ms. Kidder:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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):_____

Device Name: Attain 6216A and 6218A Product Family

Indications For Use: The Attain 6216A/6218A Product Family is intended for introducing balloon catheters into the coronary sinus or 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 K112917