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K021589

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510(K) Summary of Substantial Equivalence

Date prepared	May 13, 2002
Submitter:	Medtronic, Inc. Parkmore Business Park West Galway, Ireland.
Submission Correspondent:	Karen Reidt, RAC Sr. Product Regulation Manager 7000 Central Avenue N.E. Minneapolis, MN 55432
Telephone:	(763) 514-3914
Fax:	(763) 514-6424
E-Mail:	karen.reidt@medtronic.com

Proprietary Name:	Attain™ Access 6218A Left-heart delivery system
Common Name:	Catheter, Percutaneous
Device Classification:	Class II, 21 CFR § 870.1250
Product Code:	74 DQY

Performance Standard

Performance standards do not currently exist for these devices. None established under Section 514.

Device Description

The left-heart delivery system features two guide wires to facilitate venous access, adjustable hemostasis valves to reduce blood loss during the implant procedure, two guide catheters for passing venogram balloon catheters or appropriate leads, a guide catheter dilator to facilitate guide catheter passage, guide catheter slitters for removing guide catheters, and a guide wire clip to help contain the guide wire in the sterile field.

The Attain Access 6218A Left-heart delivery system combines devices that are either cleared for market distribution via 510(k) or are exempt from premarket notification because of Class I designation.

The key changes being made to the system are the addition of Tungsten Carbide-filled polyether block amide material to the guide catheter distal tip segment and

the addition of extra slitters and adjustable hemostasis valves in a revised system configuration.

Indications for Use

The intended use of the Medtronic Attain Access 6218A Left-heart delivery system is for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus

Substantially Equivalent Device

Attain Access 6218A Left-heart Delivery System Predicate Device

Attain Access 6218A Left-heart Delivery System Device	Predicate Device	Predicate Device Manufacturer	Predicate 510(k)
45 cm and 50 cm Guide Catheters	Medtronic Attain Access 6218 Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K012083
Guide Catheter Dilator	Medtronic Attain Access 6218 Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K012083
Adjustable Hemostasis Valve	Medtronic Attain Access 6218 Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K012083
120 cm Guide Wires	Medtronic Attain Access 6218 Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K012083
4 Fr and 6 Fr Guide Catheter Slitters	Medtronic Attain Access 6218 Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K012083
Guide Wire Clip	Class I device, exempt from premarket notification		

Summary of Studies

In vitro testing and biocompatibility/sterilization testing was performed to support substantial equivalence to the predicate device. The results of this testing indicates that the Attain Access 6218A meets all of its design and performance requirements.

Biocompatibility Information

Biocompatibility testing was performed on representative samples of Attain product. Complete testing according to ISO 10993-1 was conducted and all materials were found to be biocompatible.

Sterilization Validation

The Attain Access 6218A Left-heart delivery system is sterilized using a 100% Ethylene Oxide (ETO) sterilization process. Appropriate processes for sterilizing the devices were validated.

Conclusion (Statement of Equivalence)

Through the data and information presented, as well as similarities to a legally marketed device, Medtronic, Inc. considers the Attain Access 6218A Left-heart delivery system to be substantially equivalent to the previously discussed legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2002

Ms. Karen Reidt
Principal Regulatory Affairs Specialist
Cardiac Rhythm Management
Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432

Re: K021589
Trade Name: Attain™ Access 6218A Left-Heart Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: May 13, 2002
Received: May 15, 2002

Dear Ms. Reidt:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): ~~N/A~~ K021589

Device Name: Attain™ Access 6218A Left-heart delivery system

Indications For Use: The Attain™ Access 6218A Left-heart delivery system is intended for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021589