 K024032

DEC 3 0 2002

510(K) Summary of Substantial Equivalence

Date prepared	December 3, 2002
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Proprietary Name:	Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery
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 Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery features one (1) Muli-purpose shaped guide catheter for passing balloon catheters or appropriate leads and one (1) guide catheter dilator to facilitate guide catheter passage.

The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery contains a dilator that is cleared for market distribution via 510(k).

The key change being made to the catheter is the change in the shape of the distal section in order to respond to the needs of physician preferences and to address subtle anatomical differences between patients. Other changes include the elimination of the existing system components (i.e. adjustable hemostasis valves, guidewires, guidewire clip, guide catheter slitters) which are commercialised with

the Attain™ Access 6218A Left-heart delivery system, with the exception of the guide catheter dilator. The revised configuration of one (1) guide catheter and one (1) guide catheter dilator per package has necessitated changes to the associated packaging and labelling. In addition, the modified device will be given a new model number, Attain™ 6216A-MP.

Indications for Use

The intended use of the Medtronic Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery 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 LDS 6216A and Attain Access 6218A Left-heart Delivery System Predicate Devices

Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery	**Predicate Device**	**Predicate Device Manufacturer**	**Predicate 510(k)**
6216A-MP Multi-purpose Guide Catheter	Medtronic Attain LDS 6216A Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K021587
	Medtronic Attain Access 6218A Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K021589
Guide Catheter Dilator	Medtronic Attain Access 6218A Left-heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K021589

Summary of Studies

In vitro testing, packaging and sterilization validation testing was performed to support substantial equivalence to the predicate devices. The results of this testing indicate that the Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery meets all of its design and performance requirements.

Biocompatibility Information

The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery is biocompatible and meets the requirements of ISO 10993-1. The materials used to fabricate the Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery are identical to those used to fabricate the guide catheters of the predicate devices.

Sterilization Validation

The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery 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™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery to be substantially equivalent to the previously discussed legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2002

Medtronic, Inc.
c/o Ms. Lynn Jensen
Senior Regulatory Affairs Specialist
Cardiac Rhythm Management
7000 Central Avenue, N.E.
Minneapolis, MN 55432

Re: K024032
Trade Name: Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-Heart Delivery
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: December 3, 2002
Received: December 6, 2002

Dear Ms. Jensen:

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 (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,

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

Enclosure

Indications for Use Statement

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

Device Name: Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery

Indications For Use: The Attain™ 6216A-MP Multi-purpose Guide Catheter for Left-heart delivery 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 Sign-Off)
Division of Cardiovascular Devices

510(k) Number K024032