K032622

SEP - 3 2003

510(k) Summary of Substantial Equivalence

Date Prepared: August 25, 2003

Submitter: Medtronic, Inc.
7000 Central Avenue N.E.
Minneapolis, MN 55432

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Proprietary Name: Attain™ Prevail® Left Heart Delivery System

Common Name: Catheter, Percutaneous

Device Classification: Class II, 21 CFR § 870.1250

Product Code: 74DQY

Device Description

The Medtronic Attain™ Prevail® Left Heart Delivery System features a steerable catheter and accessories to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

The components of the Attain Prevail Left Heart Delivery System include:

- Prevail steerable catheter
- 45 cm straight guide catheter
- 50 cm straight guide catheter
- 0.016" stainless steel guide wire
- 0.035" stainless steel guide wire
- 3- way stopcock
- Universal slitter
- Introducer valve
- Guide catheter dilator
- Y-connector with adjustable hemostasis valve assembled with an extension tube
- Guide wire torque tools
- Guide wire clips

The Prevail steerable catheter features a single lumen for passage of devices up to 0.035" (0.89 mm) diameter or injection of contrast solutions. Transvenous devices with an inner diameter of 7 French (2.3 mm) or larger can be loaded on and delivered over the Prevail catheter. The catheter features a steerable distal section and is radiopaque for visibility under fluoroscopy.

The Attain Prevail Left Heart Delivery System is provided STERILE and is intended for single use only.

Indications for Use

The Attain Prevail Left Heart Delivery System is indicated to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

Substantially Equivalent Devices

	Predicate Device	**Predicate Device Manufacturer**	**Predicate 510(k)**
Catheter	Medtronic Attain Prevail Steerable Catheter Set Model 6228CTH	Medtronic	K031211
Catheter	Medtronic Attain Access Left-Heart Delivery System Model 6218A	Medtronic	K021589
Introducer Valve	Introducer Valve Model 6228VAL	Cook Vascular Incorporated	K010128
Universal Slitter	Class I device, exempt from premarket notification.		

The Attain Prevail Left Heart Delivery System uses similar technology and has similar intended uses, materials and dimensional characteristics to the predicate devices.

Summary of Studies

Verification testing included system compatibility and packaging integrity testing. The Attain Prevail Left Heart Delivery System met all specified design and performance requirements.

Biocompatibility Information

All device components were assessed for biocompatibility consistent with ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing. All specified biocompatibility requirements were met.

Sterilization Validation

The Attain Prevail Left Heart Delivery System will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion

Through the data and information presented, Medtronic, Inc. considers the Attain Prevail Left Heart Delivery System 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

SEP - 3 2003

Medtronic, Inc.
c/o Ms. Lynn Jensen
Senior Regulatory Affairs Specialist
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K032622
Trade Name: Attain™ Prevail® Left Heart Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 25, 2003
Received: August 26, 2003

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. 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 (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

510(k) Number (if known): K032622

Device Name: Attain™ Prevail® Left Heart Delivery System

Model 6228SYS

Indications for Use: The Attain™ Prevail® Left Heart Delivery System is indicated to provide a pathway for delivery of transvenous devices to the coronary sinus and coronary vasculature of the heart.

(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 K032622

(Optional Format 1-2-96)

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