AUG 2 8 2001

K012225

510(K) Summary of Substantial Equivalence

Date prepared	July 13, 2001
Submitter:	Medtronic, Inc. 7000 Central Avenue N.E. Minneapolis, MN 55432
Contact:	Karen Reidt, RAC Sr. Product Regulation Manager
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Proprietary Name:	Attain™ 6215 Venogram Balloon Catheter
Common Name:	Catheter, Flow Directed
Device Classification:	Class II, 21 CFR § 870.1240
Product Code:	74 DYG

Device Description

The Medtronic Attain 6215 Venogram balloon catheter is designed for use within the coronary sinus for infusing contrast solutions for venogram imaging. It consists of extruded polymeric tubing with two lumens (inflation and infusion) in the main body of the catheter and a 1.25 cc controlled stroke volume syringe. The inflation lumen features a luer lock and stopcock at the proximal hub. Its distal end opens into a latex balloon, which is located near the catheter tip. The infusion lumen has a luer lock at its proximal hub.

Indications for Use

The Attain™ 6215 Venogram balloon catheter is intended for use within the coronary sinus; it is intended for infusing contrast solutions into the coronary vasculature for venogram imaging. The Attain 6215 Venogram balloon catheter is intended for single use only.

Substantially Equivalent Device

The predicate device for the Attain™ 6215 Venogram balloon catheter is outlined in the following table.

Predicate Device	Predicate Device Manufacturer	Predicate 510(k)
Balloon Wedge Pressure, Angiographic	B. Braun Medical, Inc.* Allentown, PA 18103	K822806 cleared 11/1/82
Accent DG ™ Balloon Angioplasty Catheter	Cook, Inc Bloomington, IN 47402	K900677 cleared 02/22/91
Vueport ™ Coronary Sinus Balloon Occlusion Guiding Catheter	Cardima, Inc Freemont, CA 94538	K973298 cleared 06/26/98

Summary of Studies

Compatibility testing and incoming inspection of final packaged device was performed to support substantial equivalence to the predicate device. The Attain 6215 Venogram balloon catheter passed all of the in vitro specified requirements, and ensures that the Attain 6215 Venogram balloon catheter meets all of its design and performance requirements.

Clinical Use Experience

The Attain 6215 Venogram balloon catheter has been used in two Medtronic sponsored IDE clinical studies to facilitate the implantation of left ventricular leads. The Attain 6215 Venogram balloon catheter has performed as expected in the clinical environment during venogram imaging, and left ventricular lead placement via the coronary sinus.

Biocompatibility Information

Because there are no new materials or material composition changes made to the Attain 6215 Venogram balloon catheter from those used in the predicate Model WP balloon catheter manufactured by B. Braun Medical, Inc., biocompatibility testing was not repeated for the Attain 6215 Venogram balloon catheter.

Sterilization Validation

The Attain 6215 Venogram balloon catheter is sterilized using a 100% Ethylene Oxide (ETO) sterilization process. Processes appropriate for sterilizing the devices were validated.

Conclusion

Through the data and information presented, as well as similarities to legally marketed devices, Medtronic Inc, considers the Attain 6215 Venogram balloon catheter 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

AUG 2 8 2001

Ms. Karen Reidt
Medtronic, Inc.
Cardiac Rhythm Management
7000 Central Avenue NE
Minneapolis, MN 55432-3576

Re: K012225
Trade Name: Attain 6215 Venogram Balloon Catheter
Regulation Number: 21 CFR 870.1240
Regulatory Class: Class II (two)
Product Code: 74 DYG
Dated: July 13, 2001
Received: July 16, 2001

Dear Ms. Reidt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~N/A~~ K012225

Device Name: Medtronic® Attain™ 6215 Venogram balloon catheter

Indications For Use: The **Attain 6215 Venogram balloon catheter** is indicated for use within the coronary sinus; it is intended for infusing contrast solutions into the coronary vasculature for venogram imaging. The Attain 6215 Venogram balloon catheter is intended for single use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012225