K012130

AUG 2 8 2001

510(k) Summary of Substantial Equivalence

Date prepared	July 6, 2001
Submitter:	Medtronic, Inc. 7000 Central Avenue N.E. Minneapolis, MN 55432
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Proprietary Name:	Attain™ LDS 6216 Left-heart delivery system
Common Name:	Catheter, Percutaneous
Device Classification:	Class II, 21 CFR § 870.1250
Product Code:	74 DQY

Device Description

The left-heart delivery system features two guide catheters for passing venogram balloon catheters or appropriate leads an adjustable hemostasis valve to reduce blood loss during the implant procedure, a guide catheter dilator to facilitate guide catheter passage, guide catheter slitters for removing guide catheters and a percutaneous introducer kit to facilitate venous access.

The Attain LDS 6216 is intended for single use only and will be distributed independently for use with current and future leads.

The Attain LDS 6216 combines devices that are either cleared for market distribution via 510(k) or are exempt from premarket notification because of Class I designation.

Indications for Use

The intended use of the Medtronic Attain LDS 6216 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 Devices

Attain LDS 6216 Left-heart Delivery System Predicate Devices

Attain LDS 6216 Left-heart Delivery System Device	Predicate Device	Predicate Device Manufacturer	Predicate 510(k)
40 cm and 45 cm Guide Catheters	Medtronic GC IV Coronary Guiding Catheter	Medtronic Interventional Vascular (MIV) Danvers, MA 01923	K950490
	SafeSheath MSP (Same as SafeSheath CSG)	Thomas Medical Malvern, PA 19355	K003731
	GC III (Vector, Vector X) Coronary Guiding Catheter	Medtronic Interventional Vascular (MIV) Danvers, MA 01923	K950179
	Zuma Guiding Catheter	Medtronic Interventional Vascular (MIV) Danvers, MA 01923	K990707
Guide Catheter Dilator	Percutaneous Introducer Kit (Component)	MedAmicus Minneapolis, MN 55447	K965167
	SafeSheath MSP (Same as SafeSheath CSG)	Thomas Medical Malvern, PA 19355	K003731
Percutaneous Introducer Kit	Percutaneous Introducer Kit (Component)	MedAmicus Minneapolis, MN 55447	K965167
4 Fr and 6 Fr Guide Catheter Slitters	Percutaneous Introducer Kit (Component)	MedAmicus Minneapolis, MN 55447	K965167

Summary of Studies

Compatibility Testing, incoming inspection of final packaged device and package qualification testing was performed to support substantial equivalence to the predicate devices. Attain LDS 6216 passed all of the *in vitro* specified requirements, and ensures that the Attain LDS 6216 meets all of its design and performance requirements.

The Attain LDS 6216 was included in the Medtronic Model 8040 InSync System (MIRACLE) clinical investigation (G980219, approved, September 30, 1998) and Model 7272 InSync ICD System (MIRACLE ICD) clinical investigation (G990176, approved per 5-day notification, October 6, 2000). The Attain LDS 6216 Left-heart delivery system has performed as expected in the clinical environment during venogram imaging, and left ventricular lead placement via the coronary sinus.

Biocompatibility Information

Biocompatibility testing was performed on the materials which are blood contacting. Testing according to ISO 10993-1 was conducted and all materials were found to be biocompatible.

Sterilization Validation

The Attain LDS 6216 Left-heart delivery system is sterilized using a 100% Ethylene Oxide (ETO) sterilization process. Appropriate processes 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 LDS 6216 Left-heart delivery system 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: K012130
Trade Name: Attain LDS 6216 Left-Heart Delivery System
Regulation Number: 21 CFR 870.1250
Regulatory Class: Class II (two)
Product Code: 74 DQY
Dated: July 6, 2001
Received: July 9, 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 K012130

Device Name: Attain™ LDS 6216 Left-heart delivery system

Indications For Use: The **Attain LDS 6216 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 ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012130