DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 2003

Medtronic, Inc.
c/o Ms. Kristina Mollner
Sr. Regulatory Affairs Specialist
Cardiac Rhythm Management
7000 Central Avenue, NE
Minneapolis, MN 55432

Re: K032312
Trade Name: ATTAIN™ 6226DEF Deflectable Catheter Delivery System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: September 19, 2003
Received: September 22, 2003

Dear Ms. Mollner:

This letter corrects our substantially equivalent letter of October 21, 2003 regarding the designation as class III (three) in the letter. The correct class for the device is class II (two).

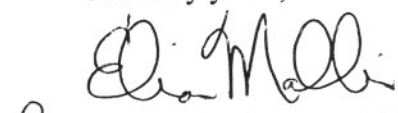
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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 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 (21 CFR Part 807); 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 the labeling regulation, please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 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,



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

Enclosure

K032312

OCT 2 1 2003

510(K) Summary of Substantial Equivalence

Date prepared	25 July, 2003
Submitter:	Medtronic Ireland Parkmore Business Park West Galway Ireland
Submission Correspondent:	Kristina Mollner Sr. Regulatory Affairs Specialist 7000 Central Avenue, N.E. Minneapolis, MN 55432
Telephone:	(763) 514-3914
Fax:	(763) 514-6424
E-Mail:	kristina.mollner@medtronic.com
Proprietary Name:	Attain™ 6226DEF Deflectable Catheter 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 6226DEF system features a percutaneous needle and syringe to access the venous insertion site, a guide wire to access the vein, a valve to reduce blood loss during the implant procedure, a deflectable catheter to introduce a transvenous device, a deflectable catheter dilator to facilitate deflectable catheter passage, and a slitter to remove the deflectable catheter.

The Attain 6226DEF Deflectable Catheter Delivery System combines devices that are either pre-amendment devices, devices that are 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 versus the predicate 10600 device are a decrease in the length of the deflectable catheter, a reduction in the stiffness of the deflectable catheter tip, and a change in the articulated shape of the catheter. The dilator length is also decreased in line with the catheter. In addition the slitters are replaced by a Universal Slitter and the adjustable hemostasis valve is replaced by an introducer valve. The entire system is packaged in a revised packaging configuration.

Indications for Use

The deflectable catheter delivery system is indicated to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart, and for introducing balloon catheters into the coronary sinus or leads into vessels of the left heart via the coronary sinus.

Substantially Equivalent Devices

Attain 6226DEF Deflectable catheter delivery system predicate devices

The design, technology, features, functions and intended use of the 6226DEF Deflectable Catheter Delivery System are substantially equivalent to the following predicate devices currently in interstate commerce.

Attain 6226DEF Deflectable Catheter Delivery System	Predicate Device	Predicate Device Manufacturer	Predicate 510(k)
Deflectable catheter	Medtronic 10600 Deflectable catheter system	Medtronic, Inc. Minneapolis, MN 55432	K013517
Guide Catheter Dilator	Medtronic 10600 Deflectable catheter system	Medtronic, Inc. Minneapolis, MN 55432	K013517
Guide Wire	Medtronic 10600 Deflectable catheter system	Medtronic, Inc. Minneapolis, MN 55432	K013517
Introducer valve	Cook 6228VAL Introducer Valve	Cook Vascular Incorporated Leechburg, PA 15656 USA	K010128
Universal Slitter	Medtronic 6228SLT Universal Slitter	Medtronic, Inc. Minneapolis, MN 55432	Class I device, exempt from premarket notification
Needle	Medtronic 10600 Deflectable catheter system	Medtronic, Inc. Minneapolis, MN 55432	K013517
Syringe	Medtronic 10600 Deflectable catheter system	Medtronic, Inc. Minneapolis, MN 55432	K013517

Additionally, the biocompatibility of the Attain 6226DEF Deflectable Catheter Delivery System is substantially equivalent to the following device.

Attain 6226DEF Deflectable Catheter Delivery System	Predicate Device	Predicate Device Manufacturer	Predicate 510(k)
Deflectable catheter	Medtronic Attain Access 6218 Left-Heart Delivery System	Medtronic, Inc. Minneapolis, MN 55432	K012083

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 6226DEF meets all of its design and performance requirements.

Biocompatibility Information

Materials/components of the Attain 6226DEF kit were evaluated for compliance to ISO10993. All materials were found to be biocompatible and in compliance to ISO10993.

Sterilization Validation

The Attain 6226DEF Deflectable catheter 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 legally marketed devices, Medtronic, Inc. considers the Attain 6226DEF deflectable catheter delivery system to be substantially equivalent to the previously discussed legally marketed predicate devices.

Indications for Use Statement

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

Device Name: Attain™ 6226DEF Deflectable catheter delivery system

Indications For Use: The deflectable catheter delivery system is indicated to provide a pathway through which diagnostic and therapeutic transvenous devices are introduced within the chambers and coronary vasculature of the heart, and 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 K032312