K102588

MAR 18 2011

510(K) SUMMARY

Date Prepared:	March 7, 2011
Trade Name of Device:	Achieve™ Mapping Catheter
Common Name:	Catheter, electrode recording, or probe, electrode recording
Classification:	Class II, 21 CFR 870.1220, Electrode Recording Catheter
Applicant:	Medtronic Ablation Frontiers 2210 Faraday Avenue, Suite 100 Carlsbad, CA 92008 USA Tel: 760-827-0007 Fax: 760-827-0020
Contact Person:	Brenda Clay Regulatory Affairs
Predicate Devices:	ProMap™, ProRhythm Lasso™, Biosense Webster

Device Description:

The Achieve™ diagnostic mapping catheter is an intra-cardiac electrophysiology recording catheter and can be used for cardiac stimulation during electrophysiology studies. The distal mapping section of the Achieve catheter is a circular loop with eight evenly spaced electrodes to map electrical conduction within the atrium. The Achieve catheter should only be used with the corresponding electrical cable for Achieve. The Achieve catheter is available with two distal loop diameter sizes described in the following table:

Model	Loop Diameter
990063-015	15 mm
990063-020	20 mm

The sterile, single use only Electrical Cable (Model 990066) provides the conduction elements from the proximal end of the Achieve Catheter handle to standard shielded ECG pins that connect into standard electrophysiology recording and pacing equipment.

Indications for Use:

The Medtronic Ablation Frontiers Achieve Mapping Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The Achieve Catheter is designed to obtain electrograms in the atrial regions of the heart.

Contraindications:
The catheter is contraindicated as follows:

- For use as an ablation device

- For use with transeptal sheaths featuring side holes larger than 1.00 mm in diameter
- Retrograde approach

Electrophysiology studies are contraindicated when the patient's underlying cardiac disease makes it likely that induced arrhythmias will be extremely difficult to terminate and carry a high risk of death, as in the following conditions:

- An active systemic infection
- Left atrial thrombus
- Pulmonary vein stents
- Prosthetic heart valve (tissue or mechanical)
- Myxoma
- Interatrial baffle or patch
- Conditions where the manipulation of the catheter within the heart would be unsafe
- Acute myocardial infarction

Technological Characteristics of the Device Compared to the Predicate Device:

The Achieve Mapping Catheter uses similar technology, has similar intended use, functions, materials and method of operation as the following predicate device(s):

Table 5-1: Characteristic Comparison

Device	**Achieve Catheter (Subject Device)**	**ProMap Catheter**	**Lasso Catheter**
Intended Use	Map intracardiac structures of the heart	Map intracardiac structures of the heart	Map intracardiac structures of the heart
Indications for Use	The Achieve is indicated for multiple electrode electrophysiological mapping of cardiac structures (i.e., recording and stimulation only). The Achieve Catheter is designed to obtain electrograms in the atrial regions of the heart.	The ProRhythm ProMap is to be used for the evaluation of cardiac arrhythmias from endocardial and intravascular sites. The ProMap coaxial mapping Catheter is typically used in Electrophysiology clinical procedures.	The LASSO Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures (i.e., recording and stimulation only). The LASSO Catheter is designed to obtain electrograms in the atrial regions of the heart.
Catheter Body Tubing	Pebax (distal body) Stainless Steel (proximal)	Unknown	Pebax
Diameter	3.3F	3F	3F
Effective Length	146cm	60 – 125cm	143cm
Number of Electrodes	8	6	10 or 20
Distal End Shape	Circular Loop	Circular Loop	Circular Loop
Loop Diameter	15 and 20mm	15 to 25mm	15 to 25mm
Loop Material	Nitinol insulated with PET (Pebax covered)	Nitinol	Unknown
Delivered through a delivery catheter	Yes	Yes	Yes

Note: Materials in the predicate devices are not known with certainty. Material equivalence is demonstrated by *in vivo* performance tests and biocompatibility tests to FDA recognized standards.

Summary of Studies:

In vitro bench testing and *in vivo* testing have been performed on the device materials and finished devices. Performance, sterilization and biocompatibility testing verified that the Achieve Mapping Catheter performs as designed and is suitable for its intended use.

Performance testing included the following:

- Torquer / Introducer: insertion testing
- Rotational motion
- Insertion and retraction with compatible delivery device
- Insertion/retraction cycling
- Loop rotation
- Rotational loading
- Electrode contact sufficient for mapping
- Atraumatic tip
- Stiffness / flexibility / buckling
- Flexion fatigue
- Torque to failure
- Simulated use testing
- Electrical testing and electrical safety testing (ISO 60601-1:2006)
- Tensile testing (ISO 10551-1:2009)
- Loop integrity
- Connector fatigue
- Corrosion resistance (ISO 10555-1:2009)

Biocompatibility testing included the following:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2002, Amend 2006)
- Intracutaneous reactivity (ISO10993-10:2002, Amend 2006))
- Systemic toxicity (ISO 10993-11:2006)
- Pyrogenicity (ISO10993-11:2006)
- Hemolysis (ISO 10993-4:2002)
- Complement activation (ISO 10993-4:2002)
- Partial thromboplastin time (PPT) (ISO 10993-4:2002)
- Platelet and leukocyte count (ISO 10993-4:2002)

The Cable has been tested and is considered safe and effective per applicable parts of BS EN 60601-1 (**2006**, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance).

Conclusion:
The data presented in this submission demonstrate that the Ablation Frontiers Achieve Mapping Catheter is substantially equivalent to the predicate devices identified in regards to device design, materials, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Ablation Frontiers
c/o Ms. Brenda Clay
Regulatory Affairs Specialist
2210 Faraday Avenue, Suite 100
Carlsbad, CA 92008

MAR 18 2011

Re: K102588
Trade Name: Achieve Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: March 11, 2011
Received: March 14, 2011

Dear Ms. Clay:

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 (240) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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4. INDICATIONS FOR USE STATEMENT

510(K) Number (if known):

Device Name: Medtronic Achieve™ Mapping Catheter

Indications for Use:

The Medtronic Ablation Frontiers Achieve Mapping Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The Mapper Catheter is designed to obtain electrograms in the atrial regions of the heart.

Prescription Use __X____ (21 CFR 801 Subpart D)	AND/OR	Over-the-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(K) Number K102588