



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 7, 2016

Abbott Electrophysiology
Dennis Pozzo
Sr. Regulatory Affairs Specialist
3368 S. Geyer Road, Suite 365
St. Louis, MO 63127

Re: K153093

Trade/Device Name: FIRMap Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD
Dated: March 4, 2016
Received: March 7, 2016

Dear Dennis Pozzo:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

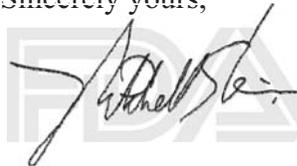
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for 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)

K153093

Device Name

FIRMap Catheter

Indications for Use (Describe)

For use in cardiac electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The FIRMap Catheter may also be used for delivery of externally generated pacing stimuli.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Appendix 1: 510(k) Summary per 21CFR §807.92

Submitter's information

Abbott Electrophysiology
3668 S. Geyer Road, Suite 365
St. Louis, MO 63127
Contact: Dennis Pozzo/Phone 314-300-6580

Device/ classification name

- Device Name: FIRMap Catheter
 - Classification/Common name: Electrode recording catheter or electrode recording probe
 - Product Code/Classification No.: MTD/21 CFR 870.1220
 - The marketed device(s) to which substantial equivalence is claimed: K130827, cleared October. 31, 2013
-

Device description

The catheter is used in cardiac electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The FIRMap Multiple Electrode Recording and Pacing Catheter may also be used for delivery of externally generated pacing stimuli.

The FIRMap catheter is delivered to the heart chamber via an intravascular sheath. After the catheter is positioned the sheath is withdrawn enough to allow the basket to expand and the electrodes to contact the heart wall.

Indications for use

For use in cardiac electrophysiology procedures to assist in the diagnosis of complex arrhythmias that may be difficult to identify using conventional mapping systems alone (i.e., linear mapping catheters). The FIRMap Catheter may also be used for delivery of externally generated pacing stimuli.

Technological characteristics

- Both the proposed and predicate FIRMap catheters contain a distal basket assembly.
- Arranged into a three dimensional shape that expands,
 - Contain an array of 64 electrodes mounted onto eight support structures called splines.
 - Each spline has 8 electrodes spaced at an equal distance along the length of the spline.
 - The splines are fixed at an equal distance labeled A through H in a clockwise direction viewed from the catheter/basket's distal tip.
 - The array orientation is displayed by use of radiopaque markers.
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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Design change The proposed device incorporates a design change to the distal spline which is intended to improve performance and manufacturability compared with the predicate device.

Device Characteristic (Technological Comparison)	Predicate FIRMap Catheter (K130827)	Proposed FIRMap Catheter
Intended Use	Intracardiac electrophysiological mapping and pacing.	Intracardiac electrophysiological mapping and pacing.
Splines		
No. of splines	8 (expanding)	8 (expanding)
Spline Material	Nitinol	Nitinol
Spline Tube Material	Pebax	Pebax
Spline radiopaque material	platinum-iridium alloy	platinum-iridium alloy
Distal spline connecting tip (tip dome and cap)	316 Stainless steel	316 Stainless steel
Distal Catheter Tubing	Polyester Shrink Tubing	Polyester Shrink Tubing
Distal Spline Tubing	Polyester Shrink Tubing	NA
Method for limiting spline movement	EDM “bowtie” feature	Extend Pebax tubing
Electrodes		
No. of electrodes	64	64
Electrode material	Gold plated copper	Gold plated copper
Electrode configuration	Unipolar or bipolar	Unipolar or bipolar
Dimensions		
Basket diameter/ Electrode spacing	40mm/ 6.8mm 50mm/ 9.0mm 60mm/ 11.2mm 70mm/13.5mm	40mm/ 6.8mm 50mm/ 9.0mm 60mm/ 11.2mm 70mm/13.5mm

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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Device Characteristic (Technological Comparison)	Predicate FIRMap Catheter (K130827)	Proposed FIRMap Catheter
Catheter shaft diameter	2.8mm	2.8mm
Working length	128cm +/-1cm	128cm +/-1cm
Recommended guide catheter	ID = 8.5 Fr.	ID = 8.5 Fr.
Electrical Rating		
Electrical rating – Typical	+/- 27V, 25mA	+/- 27V, 25mA
Dielectric strength	500V DC	500V DC
Sterilization		
Method of sterilization	EO gas	EO gas
Single use	Yes	Yes

Applicable standards

- ISO 14971: 2012, Medical Devices - Application of risk management to medical devices
- ISO 10555-1: 2012 Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements

Performance data

Bench Testing

The modification only impacts the basket subassembly of the catheter; the scope of testing was limited to confirming the mechanical integrity of the basket subassembly and its functionality.

Test Description	Acceptance Criteria	Conclusion
Basket Radial force	Variable – 95/95 Confidence/Reliability	PASS
Basket Lateral Spline Stiffness	Variable – 95/95 Confidence/Reliability	PASS
Introduction/ Withdrawal Cycling	Attribute – 95/95 Confidence/reliability per Weibull analysis	PASS
FIRMap Catheter Testing in Pancake Atrium	Attribute – 95/95 Confidence/reliability	PASS

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Appendix 1: 510(k) Summary per 21CFR §807.92, Continued

Performance data, continued

In-Vivo Testing

Evaluated the modification of the basket assembly during simulated use. No clinically significant differences in use or functionality were noted between the proposed and predicate catheters.

Conclusion

Performance testing has demonstrated that the modified FIRMap Catheter provides reasonable assurance of conformance to predicate device requirements. Therefore, it is substantially equivalent to the predicate device, safe and effective for its intended use.
