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

February 28, 2017

Abbott Electrophysiology
Dennis Pozzo
Senior Regulatory Affairs Specialist
3668 S. Geyer Road
Suite 365
St. Louis, Missouri 63127

Re: K163709
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: January 17, 2017
Received: January 18, 2017

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163709

Device Name

FIRMap Catheter

Indications for Use *(Describe)*

For use in cardiac electrophysiology procedures to assist in the diagnosis of 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5: 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 Trade 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: FIRMap Catheter, K153093, cleared April 7, 2016

Device description

The FIRMap Catheter is a sterile, single use device used to detect and record intracardiac electrical potentials and to deliver externally generated pacing stimuli. 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 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

The distal, expandable basket assembly is arranged into a three dimensional "basket" shape. The basket assembly contains 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 eight splines are fixed at an equal distance labeled A through H in a clockwise direction if viewed from the catheter/basket's distal tip. The array orientation is displayed by use of radiopaque markers. To distinguish splines under fluoroscopy, Spline A has a larger radiopaque marker next to electrode 8, Spline B has a larger marker next to electrode 7, Spline C has an additional marker next to electrode 6, and so onwards in progression to Spline G.

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Section 5: 510(k) Summary per 21CFR §807.92, Continued

Device Characteristic	Predicate RhythmView Workstation	Proposed RhythmView Workstation
Device Characteristic	**Predicate FIRMap Catheter (K153093)**	**Proposed FIRMap Catheter**
Intended Use	Intracardiac electrophysiological mapping and pacing.	Intracardiac electrophysiological mapping and pacing.
Splines expand	Yes	Yes
No. of Splines	8	8
No. of electrodes	64	64
Sterile	Yes	Yes
Method of sterilization	EO gas	EO gas
Single use	Yes	Yes
Radiopaque markers	Yes	Yes
Spline radiopaque material	platinum-iridium alloy	platinum-iridium alloy
Basket diameter/ Electrode spacing	50mm/ 9.0mm 60mm/ 11.2mm 70mm/13.5mm	50mm/ 9.0mm 60mm/ 11.2mm 70mm/13.5mm
Basket Tip	Two Piece - Tip Dome and Cap	Single Piece
Basket Tip Material	Stainless Steel	Stainless Steel

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

Since there are no electrical updates, the EMC and Electrical Safety reports referenced in K153093 still apply.

- IEC 60601-1, 3rd Edition, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

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Section 5: 510(k) Summary per 21CFR §807.92, Continued

Performance data	The following is a list of the tests conducted: Radial Strength, Lateral Strength, Insertion/Withdrawal cycling, Torque and Pancake Atrium. No animal or clinical testing was conducted. The testing has demonstrated that the FIRMap catheter provides reasonable assurance that the proposed device conforms to the appropriate requirements for its intended use. Therefore, it is substantially equivalent to the predicate device, safe and effective for its intended use.