April 23, 2018

St. Jude Medical, Inc.
Jennifer Ruether
Regulatory Affairs Manager
5050 Nathan Lane North
Plymouth, Minnesota 55442

Re: K172393
Trade/Device Name: Advisor HD Grid Mapping Catheter, Sensor Enabled
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: MTD
Dated: March 14, 2018
Received: March 16, 2018

Dear Jennifer Ruether:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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)*

K172393

Device Name

Advisor HD Grid Mapping Catheter, Sensor Enabled

Indications for Use *(Describe)*

The Advisor HD Grid Mapping Catheter, Sensor Enabled, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

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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St. Jude Medical is now Abbott.

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510(k) Number K172393

Submitter Information

Date Prepared	April 13, 2018
Submitter Name & Address	St. Jude Medical 5050 Nathan Lane North Plymouth, MN 55442 Phone: 651 756 5400 Fax: 651 756 5355
Contact Person	Jennifer Ruether Regulatory Affairs Manager

Device Identification

Trade Name	Advisor™ HD Mapping Catheter, Sensor Enabled™
Common Name	Catheter, Intracardiac Mapping, High-Density Array
Classification	21 CFR 870.1220; Electrode recording catheter or electrode recording probe; Procode MTD; Class II
Predicate Device	Primary: PentaRay NAV High Density Mapping Catheter, Biosense Webster; K120425 Secondary: Advisor FL Circular Mapping Catheter, Sensor Enabled, St. Jude Medical; K160335
Reference Application	EnSite™ Velocity™ Cardiac Mapping System v5.2 & EnSite Precision™ Cardiac Mapping System v2.2 (currently under review with FDA in a concomitant 510(k) submission)
Indications for Use	The Advisor HD Grid Mapping Catheter, Sensor Enabled, is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

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Device Description	The Advisor HD Grid Mapping Catheter, Sensor Enabled, is a sterile, single-use, irrigated, high-density mapping catheter with a 7.5F shaft and an 8F distal shaft deflectable section. It is available in a D-F bi-directional curve model that is deflected using the actuator located on the catheter handle. The catheter working length is 110 cm. The device consists of a paddle-shaped distal tip with 16 electrodes, two distal shaft ring electrodes, two magnetic sensors, polymer braided shaft, handle, fluid lumen extension with a luer, and an electrical connector. The catheter also has an introducer tool intended to compress and guide the distal paddle into, and withdraw from, the hemostasis valve of an introducer sheath. The catheter is compatible with the EnSite Velocity and EnSite Precision Cardiac Mapping Systems and other accessories, including the connecting cable and commercially available irrigation pumps.
Technological Characteristics	The Advisor HD Grid Mapping Catheter, Sensor Enabled, is similar to the predicate devices in design and performance. All catheters use multiple electrodes to facilitate electrophysiological mapping and are available in similar dimensions and curve shapes; additionally, all incorporate magnetic sensors to accommodate use with the respective compatible mapping systems. Like the PentaRay catheter, the subject device incorporates a fluid lumen for irrigation of the distal tip and is indicated for use in the atria and ventricles; the catheters differ in terms of distal tip shape, and compatible mapping systems. The Advisor HD Grid and the Advisor FL catheters share the same shaft and handle design, and are compatible with the same mapping system; due to the difference in distal tip designs, the subject device differs from the Advisor FL catheter in irrigation and indications for use. Technological differences between the subject and predicate devices in indications for use, irrigation, and system-level accuracy resulted in the same questions of safety and effectiveness.

Substantial Equivalence and Summary of Studies	The Advisor HD Grid Mapping Catheter, Sensor Enabled, is substantially equivalent to the predicate devices based on comparisons of the device functionality, technological characteristics, and intended use. The identified differences between the technological characteristics have been evaluated through the following bench, *in vivo*, and biocompatibility testing:
	• Physical and Dimensional Characteristics:
	  ○ Outer dimension
	  ○ Electrode spacing
	  ○ Paddle length
	  ○ Paddle alignment
	  ○ Deflection curve shape, angle, and planarity

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Substantial Equivalence and Summary of Studies

- Handling Characteristics:
  - Actuation force/torque
  - Freedom from play
  - Manual/adjustable lock
  - Torque response
  - Column strength
  - Paddle stiffness
- Durability Characteristics:
  - Torque and tensile strength (after conditioning)
- Performance Characteristics:
  - Irrigation pressure, leakage, flow rate, luer compliance to ISO 594-2
  - Electrical resistance, isolation, fluid ingress
  - Magnetic resistance, isolation, signal characteristics, compatibility with EnSite systems
- Compliance to ANSI/AAMI/IEC 60601:
  - Patient leakage
  - Dielectric strength
  - Defibrillation protection
  - Anchorage flex
  - Handle push
- Compliance to ISO 10555-1:
  - Radiopacity
  - Surface/visual inspection
  - Corrosion resistance
  - Tensile strength
- Compliance to ISO 109993:
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Acute Systemic Toxicity
  - Pyrogenicity
  - Hemocompatibility
  - Thrombogenicity
- *In vivo* studies:
  - GLP safety study
  - Accuracy study

All thrombogenicity testing was conducted using heparin to maintain an ACT value higher than 300; therefore, Advisor HD Grid requires use of anticoagulation for both right and left side procedures, and is labeled accordingly. The resulting evidence obtained from the design verification and validation testing did not raise new questions of safety and effectiveness, and demonstrates that the subject device is as safe and effective as the predicate devices.