September 17, 2019

Abbott Medical
Tamara Stanczak
Regulatory Affairs Project Manager
5050 Nathan Lane North
Plymouth, Minnesota 55442

Re: K192037
Trade/Device Name: Advisor VL Circular 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: DRF
Dated: July 29, 2019
Received: July 30, 2019

Dear Tamara Stanczak:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Fellman
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192037

Device Name
Advisor™ VL Circular Mapping Catheter, Sensor Enabled™

Indications for Use *(Describe)*
The Advisor VL Circular Mapping Catheter, Sensor Enabled is a steerable electrophysiology catheter with integrated sensors. The catheter is used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The catheter can be used to map the atrial 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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510(k) Summary	
510(k) Number	**K192037**
Submitter Information:	
Date Prepared:	July 29, 2019
Submitter Name & Address	Abbott Medical 5050 Nathan Lane North Plymouth, MN 55442
Contact Person	Tamara L Stanczak Regulatory Affairs Project Manager Phone: 651-756-6656 Email: tamara.stanczak@abbott.com
Device Information:	
Trade Name:	Advisor™ VL Circular Mapping Catheter, Sensor Enabled™
Common Name:	Diagnostic Electrophysiology Catheter
Class:	Class II, 21CFR870.1220
Product Code:	DRF
Classification Name:	Catheter, Electrode Recording, or Probe, Electrode Recording
Predicate Device:	Advisor FL, Circular Mapping Catheter, Sensor Enabled (K160335)
Reference Device:	Reflexion Spiral Variable Radius Catheter (K072012)
Device Description:	Advisor VL Circular Mapping Catheter, Sensor Enabled (Advisor VL) is a variable radius, circular mapping catheter. It has an adjustable 4 French (F) distal loop size with a diameter ranging from 15mm – 25mm with models containing both ten (10) equidistant or twenty (20) paired platinum-iridium electrodes. The catheter has integrated sensors with two impedance-based navigational electrodes and two magnetic sensors located at the distal end of the shaft. The catheter is intended to be used with the EnSite™ Precision™ Cardiac Mapping System.
Intended Use: (Indications for Use)	Advisor VL catheter is a steerable electrophysiology catheter with integrated sensors. The catheter is used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The catheter can be used to map the atrial regions of the heart.
Comparison to Predicate Devices	The Advisor VL is substantially equivalent to the predicate devices based on comparisons of the device functionality, technological

510(k) Summary	
510(k) Number	**K192037**
	characteristics, and intended use. The differences in loop diameter and number of electrodes between Advisor VL and Advisor FL have been evaluated through bench, in vivo, and biocompatibility testing. Bench and animal testing demonstrated that the subject device is substantially equivalent to the predicate device. Results from bench, in vivo, and biocompatibility testing did not result in new questions with regard to safety and effectiveness of the device.
Summary on Non-Clinical Tests	Bench and animal testing was performed to verify the device met the pre-determined acceptance criteria. The following tests were performed: • Patient Leakage • Dielectric Strength • Defibrillation Protection • Anchorage Flex • Handle Push • Radiopacity • Biocompatibility • Surface • Corrosion Resistance • Tensile • Loop Characteristics • Shaft Properties • Functional • Functional Simulated Use • Electrical Properties • Visualization and Navigation • Sterilization/ Microbiology • Packaging • Shelf Life • GLP Animal Safety • Human Factors
Statement of Equivalence	The Advisor VL has the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device and predicate device has been shown to be substantially equivalent.