July 9, 2024

Abbott Medical
Samantha Stretar
Senior Regulatory Affairs Specialist
5050 Nathan Lane North
Plymouth, Minnesota 55442

Re: K241372
Trade/Device Name: Advisor™ HD Grid X 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: July 2, 2024
Received: July 2, 2024

Dear Samantha Stretar:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

for Marco Cannella -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241372

Device Name

Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™

Indications for Use *(Describe)*

The Advisor™ HD Grid X 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This 510(k) summary is prepared in accordance with the requirements of 21 CFR §807.92.

510(k) Information	
510(k) Number	K241372
510(k) Type	Special 510(k)
Date Prepared	14-May-2024
Submitter Information	
Manufacturer Name and Address	Abbott Medical 5050 Nathan Lane North Plymouth, MN 55442 USA
Phone Number	651-756-5833
Contact Person	Samantha Stretar Senior Regulatory Affairs Specialist
Device Information	
Trade Name	Advisor™ HD Grid X Mapping Catheter, Sensor Enabled™
Common Name	Catheter, Intracardiac Mapping, High-Density Array
Class	II
Classification Name	21 CFR 870.1220 Electrode recording catheter or electrode recording probe
Product Code	MTD – Catheter, Intracardiac Mapping, High-Density Array
Predicate Device	Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (K172393, cleared 23-Apr-2018)
Reference Device	Advisor™ HD Grid Mapping Catheter, Sensor Enabled™ (K202066, cleared 25-Nov-2020)
Device Description	The Advisor™ HD Grid X 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 paddle magnetic sensors, two distal shaft ring electrodes, two shaft magnetic sensors, polymer braided shaft, handle, fluid lumen extension with a luer, and an electrical connector. The catheter also has an insertion tool intended to compress and guide the distal paddle into, and withdraw from, the hemostasis valve of an introducer sheath. The catheter is intended to be used with the EnSite™ X EP System and other accessories, including the connecting cable and commercially available irrigation pumps.

510(k) Information	
Indications for Use	The Advisor™ HD Grid X 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.
Predicate Comparison	
Comparison of Technological Characteristics	The subject device has the same intended use, indications for use, and principles of operation as the predicate device. The subject device has substantially equivalent technological characteristics to the predicate device. Like the predicate, the subject device incorporates two magnetic sensors in the catheter shaft. The subject device also includes two magnetic sensors in the outer splines of the distal tip paddle assembly. Additional catheter components were modified from the predicate to accommodate the addition of the magnetic sensors within the paddle, improve manufacturability, and improve material stability for continuous improvement purposes. The predicate and subject device have the same working length, shaft French size, and electrode spacing.
Non-Clinical Testing Summary	Bench design verification activities were performed and met their respective acceptance criteria to ensure that the device in scope of this submission is substantially equivalent to the predicate. Testing included dimensional, visual, mechanical integrity, simulated use, electrical, packaging, and shelf-life testing to assess substantial equivalence. Additionally, biocompatibility testing was conducted per the voluntary consensus standards under ISO 10993 and met all the biocompatibility endpoints for a medical device category for an external communicating medical device with limited (≤24 hour) circulating blood contact.
Statement of Equivalence	The subject device has the same intended use, indications for use, and principles of operation as the predicate device. The subject device has similar technological characteristics to the predicate device and the completed bench design verification testing and biocompatibility testing provides objective evidence that the subject device is at least as safe and effective as the predicate, and therefore, is substantially equivalent to the predicate.