



September 3, 2020

Innovative Health, LLC.
Amanda Babcock
Regulatory Affairs Manager
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K200212

Trade/Device Name: Reprocessed 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: NLG
Dated: July 31, 2020
Received: August 3, 2020

Dear Amanda Babcock:

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
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

The item number included in the scope of this submission is as follows:

Item Number	Description	Usable Length (cm)	French Size	Curve	Spacing (mm)	Electrodes	System Compatibility
D-AVHD-DF16	Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled	110	8F	DF	3	16	EnSite Velocity and EnSite Precision Cardiac Mapping Systems

Indications for Use

510(k) Number (if known)

K200212

Device Name

Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled

Indications for Use (Describe)

The Reprocessed 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.

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
PRASStaff@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

As required by 21 CFR 807.92(c)

Submitter's Name and Address:

Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257

Contact Name and Information:

Amanda Babcock
Regulatory Affairs Manager
Innovative Health, LLC.
(480) 525-5911 (office)
(888) 965-7705 (fax)
ababcock@innovative-health.com

Date prepared:

August 21, 2020

Device Information:

Trade/Proprietary Name: Reprocessed Advisor High Density (HD) Grid Mapping Catheter, Sensor Enabled
Common or Usual Name: Diagnostic Electrophysiology Mapping Catheter
Classification Name: Electrode Recording Catheter or Electrode Recording Probe
Classification Number: Class II, 21 CFR 870.1220
Product Code: NLG

Predicate Device:

510(k) Number	Device	Manufacturer
K172393	Advisor HD Grid Mapping Catheter, Sensor Enabled	St. Jude Medical

Reference Device:

510(k) Number	Device	Manufacturer
K181458	Reprocessed Advisor FL, Sensor Enabled, Circular Mapping Catheter	Innovative Health, LLC.
K190785	Reprocessed PentaRay Nav eco High-Density Mapping Catheter	Innovative Health, LLC.

Device Description:

The Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled, is an irrigated, steerable, flexible, insulated electrophysiology catheter constructed of thermoplastic elastomer material and noble metal electrodes. The shaft curvature is manipulated by the control mechanism located on the handle at the catheter's proximal end. To adjust the curve on the catheter, use the actuator to deflect the catheter in either direction. The catheter is compatible with St. Jude Medical (Abbott) visualization and 3D navigation systems.

The item number in scope of this submission is as follows:

Item Number	Description	Usable Length (cm)	French Size	Curve	Spacing (mm)	Electrodes	System Compatibility
D-AVHD-DF16	Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled	110	8F	DF	3	16	EnSite Velocity and EnSite Precision Cardiac Mapping Systems

Table 1: Device Scope

Indications for Use:

The Reprocessed 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.

Technological Characteristics:

The purpose, design, materials, function, and intended use of the Reprocessed Advisor HD Grid Mapping Catheter (Sensor Enabled) are identical to the predicate device. There are no changes to the claims, clinical applications, patient populations, performance specifications, or method of operation. In addition, Innovative Health’s reprocessing of the Catheter includes removal of visible soil and decontamination. Each device is inspected and function tested prior to packaging and labeling.

Functional and Safety Testing:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional testing
 - Visual Inspection
 - Dimensional Verification
 - Electrical Continuity
 - Simulated Use
 - Mechanical Characteristics
- Electrical Safety Testing
 - Dielectric and Current Leakage
- Packaging Validation

The Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled, is reprocessed no more than one (1) time. Each device is marked, serialized and tracked. After the device has reached the maximum number of reprocessing cycles, the device is rejected from further reprocessing. Reprocessing is performed only by Innovative Health. Innovative Health restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:

Innovative Health concludes that the Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled, is as safe and effective as the predicate devices described herein.