November 18, 2021

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

Re: K211662
Trade/Device Name: Reprocessed IntellaMap Orion High Resolution Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLG
Dated: October 19, 2021
Received: October 20, 2021

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,

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

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

Item Number	Description	Usable Length (cm)	French Size	Curve	Electrodes
M004RC64S0	Reprocessed IntellaMap Orion High Resolution Mapping Catheter	115	8.5F	180, Bidirectional	64

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211662

Device Name
Reprocessed IntellaMap Orion High Resolution Mapping Catheter

Indications for Use *(Describe)*
The Reprocessed IntellaMap Orion High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures 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.

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SECTION 5: 510(k) SUMMARY

As required by 21 CFR 807.92

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:
May 28, 2021

Device Information:

Trade/Proprietary Name:	Reprocessed IntellaMap Orion High Resolution Mapping Catheter
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
K192360	IntellaMap Orion High Resolution Mapping Catheter	Boston Scientific Corporation

Reference Device:

510(k) Number	Device	Manufacturer
K200212	Reprocessed Advisor HD Grid Mapping Catheter, Sensor Enabled	Innovative Health, LLC.

Device Description:
The Reprocessed IntellaMap Orion High Resolution Mapping Catheter is an 8.5F(ø 2.82 mm), 115 cm working length, 64-electrode steerable catheter. The basket-shaped distal region consists of 8 splines that comprise the electrode array. The proximal end has a handle that extends to a cable with a connector. The handle includes bi-directional articulation controls and a deployment slider that activates the electrode array into a basket shape once inside the heart. A flushing port extends from the back of the connector for connection to a continuous pressurized saline drip. The catheter is supplied with an 8.5F insertion sleeve for insertion through the hemostasis valve of an introducer sheath. A sensor in the catheter tip enables the position of the distal region of the catheter to be tracked in space when used with the Rhythmia Mapping System.

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

Item Number	Description	Usable Length (cm)	French Size	Curve	Electrodes
M004RC64S0	Reprocessed IntellaMap Orion High Resolution Mapping Catheter	115	8.5F	180, Bidirectional	64

Table 5.1: Device Scope

Indications for Use:
The Reprocessed IntellaMap Orion High Resolution Mapping Catheter is indicated for electrophysiological mapping (recording or stimulating only) of the cardiac structures of the heart.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed IntellaMap Orion High Resolution Mapping Catheter 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 of the device and lumen. Each device (including the lumen) 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 IntellaMap Orion High Resolution Mapping Catheter. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional testing
    - Visual Inspection
    - Dimensional Verification
    - Dynamic Continuity
    - Simulated Use
    - Leak/Occlusion
    - Inner lumen occlusion
    - Mechanical Characteristics
- Electrical Safety Testing
    - Dielectric and Current Leakage
- Packaging Validation

The Reprocessed IntellaMap Orion High Resolution Mapping Catheter 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 IntellaMap Orion High Resolution Mapping Catheter is substantially equivalent to the predicate devices described herein.