March 5, 2021

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

Re: K203261
Trade/Device Name: Reprocessed Inquiry Steerable Diagnostic EP Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF, NHL
Dated: February 5, 2021
Received: February 8, 2021

Dear Amanda Babcock:

(NOTE: Reprocessed SUD device types require a separate attachment of the list of all models cleared in the submission. A corrected SE letter will be required if the attachment is omitted.)

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 and Part 809); 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,

Jessica Paulsen
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 following device models are included in the scope of this 510(k) submission:

Item Number	Number of Electrodes	French Size	Electrode Spacing (mm)	Curve	Usable Length (cm)
81530	10	4F	2	Medium	110
81531	10	4F	2-5-2	Medium	110
81532	10	4F	2-5-2	Large	110
81534	10	4F	5	Large	110
81537	10	4F	25	M(SC)(60)	60
81871	8	5F	2	Medium	110
81872	8	5F	2-5-2	Medium	110
81540	4	4F	2-5-2	Medium	110
81542	4	4F	5	Medium	110
81543	4	4F	2-5-2	Large	110
81472	4	5F	2-5-2	Medium	110
81473	4	5F	5	Medium	110
81474	4	5F	2-5-2	Large	110
81483	4	5F	5	E(HIS)	110
81402	4	6F	2-5-2	Medium	110
81403	4	6F	5	Medium	110
81404	4	6F	2-5-2	Large	110
81405	4	6F	5	Large	110
81417	4	6F	5	X-Large	110
81418	4	6F	2-5-2	X-Large	110
81102	10	6F	2-5-2	Medium	110
81104	10	6F	2-5-2	Large	110
81105	10	6F	2-5-2	X-Large	110
81107	10	6F	5	Large	110
81520	10	6F	2	X-Large	110
81524	10	6F	2	Large	110
81945	10	6F	2-5-2	Large	110
81947	10	6F	5	Medium/ Large	110
81504	10	6F	5	Medium	110
81801	8	6F	2	Medium	110
81802	8	6F	2-5-2	Medium	110
81807	8	6F	2	Large	110
81809	8	6F	2-5-2	Large	110
81516	8	6F	2-5-2	L1	110
81171	10	5F	2	Medium	110
81172	10	5F	2-5-2	Medium	110
81174	10	5F	2-5-2	Large	110
81223	10	5F	2-50-3	X-Large	110
81224	10	5F	2-30-3	Medium	110
81202	20	7F	2-10-2	XX-Large	110
81207	20	7F	5	Super Large	110
81209	20	7F	2-5-2	Super Large	110

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)*
K203261

Device Name
Reprocessed Inquiry Steerable Diagnostic Electrophysiology (EP) Catheter

Indications for Use *(Describe)*
The Reprocessed Inquiry Steerable Diagnostic Electrophysiology Catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies. The catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle.

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.

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SECTION 5: 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
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Innovative Health, LLC.
(480) 525-5911 (office)
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ababcock@innovative-health.com

Date prepared:
November 4, 2020

Device Information:

Trade/Proprietary Name:	Reprocessed Inquiry Steerable Diagnostic Electrophysiology Catheters
Common Name:	Diagnostic Electrophysiology Catheter
Classification Name:	Catheter, Recording, Electrode, Reprocessed
Classification Number:	Class II, 21 CFR 870.1220
Product Code:	NLH

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K171277	Reprocessed Inquiry Steerable Diagnostic EP Catheter	Innovative Health, LLC.
K982232	Modification of the IBI-1100 Steerable Electrophysiology Catheter System	Irvine Biomedical, Inc.
K961924	IBI-1100 Steerable Electrophysiology Catheter System	Irvine Biomedical, Inc.

Device Description:
The Reprocessed Inquiry Steerable Diagnostic Electrophysiology Catheters are flexible, insulated catheters constructed of thermoplastic elastomer material and noble metal electrodes. The tip of the steerable catheters may be manipulated with the control mechanism located in the handle of the proximal end of the catheter.

The item numbers included in the scope of this submission are as follows:

Item Number	Number of Electrodes	French Size	Electrode Spacing (mm)	Curve	Usable Length (cm)
81530	10	4F	2	Medium	110
81531	10	4F	2-5-2	Medium	110
81532	10	4F	2-5-2	Large	110
81534	10	4F	5	Large	110
81537	10	4F	25	M(SC)(60)	60
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81418	4	6F	2-5-2	X-Large	110
81102	10	6F	2-5-2	Medium	110
81104	10	6F	2-5-2	Large	110
81105	10	6F	2-5-2	X-Large	110
81107	10	6F	5	Large	110
81520	10	6F	2	X-Large	110
81524	10	6F	2	Large	110
81945	10	6F	2-5-2	Large	110
81947	10	6F	5	Medium/ Large	110
81504	10	6F	5	Medium	110
81801	8	6F	2	Medium	110
81802	8	6F	2-5-2	Medium	110
81807	8	6F	2	Large	110
81809	8	6F	2-5-2	Large	110
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81172	10	5F	2-5-2	Medium	110
81174	10	5F	2-5-2	Large	110
81223	10	5F	2-50-3	X-Large	110
81224	10	5F	2-30-3	Medium	110

Item Number	Number of Electrodes	French Size	Electrode Spacing (mm)	Curve	Usable Length (cm)
81202	20	7F	2-10-2	XX-Large	110
81207	20	7F	5	Super Large	110
81209	20	7F	2-5-2	Super Large	110

Table 1: Item Numbers in Scope

This 510(k) increases the Reprocessing Cycles for the devices cleared under K171277 from one (1) to three (3).

Indications for Use:
The Reprocessed Inquiry Steerable Diagnostic Electrophysiology Catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiology studies. The catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Inquiry Steerable Diagnostic Electrophysiology (EP) Catheters are identical to the predicate devices. There are no changes to the claims, clinical applications, patient population, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of these devices 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 Inquiry Steerable Diagnostic EP Catheter for three (3) reprocessing cycles. This included the following:

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

The Reprocessed Inquiry Steerable Diagnostic EP Catheters are reprocessed no more than three (3) times. Each device is marked 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.

Predicate Comparison:
A comparison of the device and reprocessing methods with the predicates are provided in the table below:

	K203261	K171277	K982232	K961924
Device:	Identical	Identical	Identical	Identical
Reprocessing Cycles:	3	1	0	0
Reprocessing Method:	Change to processing parameters and method. Shelf life change.	Cleared/validated process	N/A	N/A
Sterilization:	Change to release method. No change to the sterilization method or SAL.	Cleared/validated process	N/A	N/A
Routine Monitoring:	Change to frequency and adjustment of limits.	Cleared process	N/A	N/A

Conclusion:
Innovative Health concludes that the Reprocessed Inquiry Steerable Diagnostic EP Catheters are as safe and effective as the predicate devices described herein.