February 22, 2019

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

Re: K182488
Trade/Device Name: Reprocessed Response Diagnostic Electrophysiology Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: February 1, 2019
Received: February 4, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

The following item numbers are included in the scope of this submission (K182488):

Description	Item Number	Number of Electrodes	French Size	Electrode Spacing (mm)	Curve Type	Usable Length (cm)
Response Diagnostic Electrophysiology Catheter	401381	10	6	2-8-2	CSL	120
	401353	10	6	2-8-2	CSL	65
	401392	10	6	2-2-2	CSL	120
	401399	10	6	5-5-5	CSL	120
	401400	10	6	5-5-5	CSL	65
	401360	6	5	2-5-2	JSN	120
	401317	2	6	10	CRD	120
	401318	2	6	10	JSN	120
	401305	10	6	2-5-2	CRD	120
	401306	10	6	2-5-2	JSN	120
	401308	10	6	2-5-2	CRD	65
	401309	10	6	2-5-2	JSN	65
	401310	10	6	2-5-2	DAO	65
	401311	10	6	2-2-2	CRD	120
	401312	10	6	2-2-2	JSN	120
	401150	10	6	2-1-1-10-1-1-1-1-1	CRD	120
	401271	6	6	2-5-2	JSN	120
	401275	6	6	2-2-2	CRD	120
	401276	6	6	2-2-2	JSN	120
	401278	6	6	2-2-2	CRD	65
	401281	6	6	5-5-5	CRD	120
	401282	6	6	5-5-5	JSN	120
	401425	6	6	5-5-5-150-5	CRD	120
	401386	6	6	5-5-5	CSL	120
	401206	4	5	10	CRD	120
	401207	4	5	10	JSN	120
	401222	4	5	5	CRD	120
	401223	4	5	5	JSN	120
	401210	4	6	10	CRD	120
	401211	4	6	10	JSN	120
	401212	4	6	10	DAO	120
	401226	4	6	5	CRD	120
	401356	4	6	5	CRD-1	120
	401227	4	6	5	JSN	120
	401357	4	6	5	JSN-1	120
	401228	4	6	5	DAO	120
	401329	4	6	5	DAO-1	120
	401260	4	6	2-5-2	CRD	120
	401261	4	6	2-5-2	JSN	120
	401154	4	6	5	CRD	120
	401155	4	6	5	JSN	120
	401156	4	6	5	DAO-1	120
	401158	4	6	10	CRD	120

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)*

K182488

Device Name
Reprocessed Response Diagnostic Electrophysiology (EP) Catheter

Indications for Use *(Describe)*
The Reprocessed Response Diagnostic Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

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."

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

Date prepared:
September 10, 2018

Device Information:

Trade/Proprietary Name:	Reprocessed Response 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) Device	Manufacturer
K151622	Response Electrophysiology Catheter	St. Jude Medical
K161827	Reprocessed Response Diagnostic Electrophysiology Catheter	Innovative Health, LLC.

Device Description:
The Reprocessed Response Diagnostic Electrophysiology Catheters are manufactured in various fixed curves and electrode spacing for electrophysiological mapping for the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

The item numbers in scope of this submission are as follows (next page):

Description	Item Number	Number of Electrodes	French Size	Electrode Spacing (mm)	Curve Type	Usable Length (cm)
Response Diagnostic Electrophysiology Catheter	401381	10	6	2-8-2	CSL	120
	401353	10	6	2-8-2	CSL	65
	401392	10	6	2-2-2	CSL	120
	401399	10	6	5-5-5	CSL	120
	401400	10	6	5-5-5	CSL	65
	401360	6	5	2-5-2	JSN	120
	401317	2	6	10	CRD	120
	401318	2	6	10	JSN	120
	401305	10	6	2-5-2	CRD	120
	401306	10	6	2-5-2	JSN	120
	401308	10	6	2-5-2	CRD	65
	401309	10	6	2-5-2	JSN	65
	401310	10	6	2-5-2	DAO	65
	401311	10	6	2-2-2	CRD	120
	401312	10	6	2-2-2	JSN	120
	401150	10	6	2-1-1-10-1-1-1-1-1	CRD	120
	401271	6	6	2-5-2	JSN	120
	401275	6	6	2-2-2	CRD	120
	401276	6	6	2-2-2	JSN	120
	401278	6	6	2-2-2	CRD	65
	401281	6	6	5-5-5	CRD	120
	401282	6	6	5-5-5	JSN	120
	401425	6	6	5-5-5-150-5	CRD	120
	401386	6	6	5-5-5	CSL	120
	401206	4	5	10	CRD	120
	401207	4	5	10	JSN	120
	401222	4	5	5	CRD	120
	401223	4	5	5	JSN	120
	401210	4	6	10	CRD	120
	401211	4	6	10	JSN	120
	401212	4	6	10	DAO	120
	401226	4	6	5	CRD	120
	401356	4	6	5	CRD-1	120
	401227	4	6	5	JSN	120
	401357	4	6	5	JSN-1	120
	401228	4	6	5	DAO	120
	401329	4	6	5	DAO-1	120
	401260	4	6	2-5-2	CRD	120
	401261	4	6	2-5-2	JSN	120
	401154	4	6	5	CRD	120
	401155	4	6	5	JSN	120
	401156	4	6	5	DAO-1	120
	401158	4	6	10	CRD	120

Table 5.1: Device Scope

Indications for Use:
The Reprocessed Response Diagnostic Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Response 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 Response Diagnostic EP Catheter. 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 Response 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.

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