December 11, 2019

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

Re: K191880
Trade/Device Name: Reprocessed Achieve Advance Mapping 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: November 12, 2019
Received: November 13, 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/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,

Nicole Gillette
Acting 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 following device models are included in the scope of this 510(k) submission:

Item Number	Device Description	Electrodes	Loop Diameter (mm)	Spacing (mm)	French Size	Total Length (cm)	Usable Length (cm)
2ACH15	Achieve Advance Mapping Diagnostic EP Catheter	8	15	4	3.3F	165	146
2ACH20	Achieve Advance Mapping Diagnostic EP Catheter	8	20	6	3.3F	165	146
2ACH25	Achieve Advance Mapping Diagnostic EP Catheter	10	25	6	3.3F	165	146

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)*
K191880

Device Name
Reprocessed Achieve Advance Mapping Diagnostic Electrophysiology Catheter

Indications for Use *(Describe)*
The Reprocessed Achieve Advance Mapping Diagnostic Electrophysiology Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The catheter is designed to obtain electrograms in the atrial 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.

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

Date prepared:
July 12, 2019

Device Information:

Trade/Proprietary Name:	Reprocessed Achieve Advance Mapping Diagnostic Electrophysiology Catheter
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
K162892	Achieve Advance Mapping Electrophysiology Catheter	Medtronic

Device Description:
The Reprocessed Achieve Advance Mapping Diagnostic Electrophysiology Catheter is an intra-cardiac electrophysiology (EP) recording catheter and can be used for cardiac stimulation during electrophysiology studies. The distal mapping section of the mapping catheter is a circular loop with eight or ten evenly spaced electrodes to map electrical conduction between the left atrium and the pulmonary veins.

The reprocessed mapping catheter is compatible for use with, and may be used to support and position, all catheters in the Medtronic Arctic Front CryoAblation Catheter family. Refer to the applicable Medtronic Arctic Front Technical Manual for additional instructions for use.

The reprocessed mapping catheter should only be used with the Medtronic catheter connecting cable (Model 2ACHC), which interfaces with standard electrophysiology recording equipment. For cable instructions, see the Medtronic 2ACHC catheter connecting cable instructions for use.

Only the catheter is the subject of this submission. Any other related equipment is not included in the scope of this submission.

Indications for Use:
The Reprocessed Achieve Advance Mapping Diagnostic Electrophysiology Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The catheter is designed to obtain electrograms in the atrial regions of the heart.

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

Item Number	Device Description	Electrodes	Loop Diameter (mm)	Spacing (mm)	French Size	Total Length (cm)	Usable Length (cm)
2ACH15	Achieve Advance Mapping Diagnostic EP Catheter	8	15	4	3.3F	165	146
2ACH20	Achieve Advance Mapping Diagnostic EP Catheter	8	20	6	3.3F	165	146
2ACH25	Achieve Advance Mapping Diagnostic EP Catheter	10	25	6	3.3F	165	146

Table 5.1: Device Scope

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Achieve Advance Mapping Diagnostic Electrophysiology (EP) Catheter is identical to the predicate device. There are no changes to the claims, clinical applications, patient population, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of this device 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 Achieve Advance Mapping 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 Achieve Advance Mapping Diagnostic EP Catheter is reprocessed no more than two (2) times. 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 Achieve Advance Mapping Diagnostic EP Catheter is as safe and effective as the predicate device described herein.