October 30, 2019

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

Re: K191170
Trade/Device Name: Reprocessed Reflexion Spiral Bi-Directional Variable Radius 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: September 30, 2019
Received: October 1, 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
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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:

Description	Item Number	Usable Length (cm.)	Number of Electrodes	Electrode Spacing (mm)	Catheter French Size	Loop Adjustment (mm)	Distal Reach
Reflexion Spiral Bi-Directional Variable Radius EP Catheter	D402893	99	20	1-4-1	7	15 to 25	Symmetric
	D402865	99	10	6.3	7	15 to 25	Symmetric
	402804	99	20	1-4-1	7	15 to 25	Asymmetric

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)*
K191170

Device Name
Reprocessed Reflexion Spiral Bi-Directional Variable Radius Electrophysiology (EP) Catheter

Indications for Use *(Describe)*
The Reprocessed Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The catheter is to be used to map 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.

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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.
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ababcock@innovative-health.com

Date prepared:
April 30, 2019

Device Information:

Trade/Proprietary Name:	Reprocessed Reflexion Spiral Bi-Directional Variable Radius EP Catheter
Common or Usual Name:	Diagnostic Electrophysiology Catheter
Classification Name:	Electrode Recording Catheter or Electrode Recording Probe
Classification Number:	Class II, 21 CFR 870.1220
Product Code:	NLH

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K072012	Reflexion Spiral Variable Radius Catheter	St. Jude Medical

Device Description:
The Reprocessed Reflexion Spiral Bi-Directional Variable Radius Electrophysiology Mapping Catheter (hereinafter Reflexion Spiral catheter) is a flexible, bi-directional, variable radius loop electrophysiology catheter constructed of a polymer shaft that incorporates platinum electrodes. The Reflexion Spiral catheter has a loop and a proximal handle that contains a shaft actuator mechanism for varying the bi-directional (90°/180° minimum) distal portion of the shaft, a loop actuator mechanism for varying the loop diameter from approximately 25 mm to approximately 15 mm, and an electrical connector.

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

Description	Item Number	Usable Length (cm.)	Number of Electrodes	Electrode Spacing (mm)	Catheter French Size	Loop Adjustment (mm)	Distal Reach
Reflexion Spiral Bi-Directional Variable Radius EP Catheter	D402893	99	20	1-4-1	7	15 to 25	Symmetric
	D402865	99	10	6.3	7	15 to 25	Symmetric
	402804	99	20	1-4-1	7	15 to 25	Asymmetric

Table 5.1: Device Scope

Indications for Use:
The Reprocessed Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The catheter is to be used to map the atrial regions of the heart.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Reflexion Spiral catheter are identical to the predicate devices. 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 Reprocessed Reflexion Spiral 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 Reflexion Spiral catheter are reprocessed no more than one (1) time. 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 Reflexion Spiral catheter is as safe and effective as the predicate devices described herein.