August 23, 2019

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

Re: K190127
Trade/Device Name: Reprocessed Livewire Steerable 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: July 23, 2019
Received: July 24, 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,

Mark Fellman
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:

Item Number	Device Description	Electrodes	Spacing (mm)	Curve Type	French Size	Usable Length (cm)
401582	Livewire Steerable Diagnostic EP Catheter	10	2-5-2	Med Sweep	7F	115
401932	Livewire Steerable Diagnostic EP Catheter	20	2-8-2-(60)-2-8-2	Super Lrg Curl	7F	95
401918	Livewire Steerable Diagnostic EP Catheter	20	2-20-2-2-2-2-2-2-2-2-2-2-2-25-2-25-2-25-2	Super Lrg Curl	7F	95
401580	Livewire Steerable Diagnostic EP Catheter	6	2-5-2	Med Sweep	7F	115
401581	Livewire Steerable Diagnostic EP Catheter	8	2-5-2	Med Sweep	7F	115
401938	Livewire Steerable Diagnostic EP Catheter	10	5-5-5	Med Sweep	5F	115
401939	Livewire Steerable Diagnostic EP Catheter	10	2-2-2	Med Sweep	5F	115
401940	Livewire Steerable Diagnostic EP Catheter	10	2-5-2	Med Sweep	5F	115
401941	Livewire Steerable Diagnostic EP Catheter	10	2-8-2	Extra Lrg Curl	5F	115
401990	Livewire Steerable Diagnostic EP Catheter	10	2-2-2	Extra Lrg Curl	5F	115
401991	Livewire Steerable Diagnostic EP Catheter	10	2-5-2	Extra Lrg Curl	5F	115
401575	Livewire Steerable Diagnostic EP Catheter	10	2-5-2	Med Sweep	6F	115
401915	Livewire Steerable Diagnostic EP Catheter	10	2-5-2	Extra Lrg Curl	6F	115
401923	Livewire Steerable Diagnostic EP Catheter	10	2-2-2	Extra Lrg Curl	6F	115
401926	Livewire Steerable Diagnostic EP Catheter	10	2-8-2	Extra Lrg Sweep CSL	6F	115
401904	Livewire Steerable Diagnostic EP Catheter	20	2-10-2	Super Lrg Curl	7F	95
401905	Livewire Steerable Diagnostic EP Catheter	20	5-5-5	Super Lrg Curl	7F	95
401914	Livewire Steerable Diagnostic EP Catheter	20	2-5-2	Super Lrg Curl	7F	95
401908	Livewire Steerable Diagnostic EP Catheter	20	2-2-2	Med Curl	7F	115
401917	Livewire Steerable Diagnostic EP Catheter	8	2-2-2	Med Sweep	6F	115
401949	Livewire Steerable Diagnostic EP Catheter	8	2-2-2	Lrg Sweep	6F	115
401600	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Med Sweep	6F	115
401603	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Med Curl	6F	115
401572	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Med Sweep	6F	115
401606	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Lrg Sweep	6F	115
401933	Livewire Steerable Diagnostic EP Catheter	4	5-5-5	Med Sweep	6F	115

(Continued on the following page)

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

Item Number	Device Description	Electrodes	Spacing (mm)	Curve Type	French Size	Usable Length (cm)
401934	Livewire Steerable Diagnostic EP Catheter	4	5-5-5	Lrg Sweep	6F	115
401576	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Sml Sweep	7F	115
401577	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Med Sweep	7F	115
401578	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Lrg Sweep	7F	115
401586	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Sml Curl	7F	115
401587	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Med Curl	7F	115
401588	Livewire Steerable Diagnostic EP Catheter	4	2-5-2	Lrg Curl	7F	115
401652	Livewire Steerable Diagnostic EP Catheter	8	2-2-2	Med Sweep CRD-2	5F	115
401653	Livewire Steerable Diagnostic EP Catheter	6	2-5-2	Med Sweep CRD2	5F	115
401654	Livewire Steerable Diagnostic EP Catheter	6	5	Med Sweep CRD-2	5F	115

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)*
K190127

Device Name
Reprocessed Livewire Steerable Diagnostic Electrophysiology Catheter

Indications for Use *(Describe)*
The Reprocessed Livewire Steerable Diagnostic Electrophysiology Catheter 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.

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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)
(888) 965-7705 (fax)
ababcock@innovative-health.com

Date prepared:
January 25, 2019

Device Information:

Trade/Proprietary Name:	Reprocessed Livewire 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) Device	Manufacturer
K160242	Reprocessed Livewire Steerable Diagnostic EP Catheter	Innovative Health, LLC.
K151622	Livewire Electrophysiology Catheter	St. Jude Medical

Device Description:
The Reprocessed Livewire Steerable Diagnostic Electrophysiology Catheter is a flexible electrode catheter constructed of a polyurethane insulation/shaft and incorporates platinum electrodes. The active tip may be manipulated by remote means located at the proximal end of the catheter.

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

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

Item Number	Device Description	Electrodes	Spacing (mm)	Curve Type	French Size	Usable Length (cm)
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401653	Livewire Steerable Diagnostic EP Catheter	6	2-5-2	Med Sweep CRD2	5F	115
401654	Livewire Steerable Diagnostic EP Catheter	6	5	Med Sweep CRD-2	5F	115

Table 5.1: Device Scope

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed Livewire 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 Livewire Steerable 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 Livewire Steerable Diagnostic EP Catheters are reprocessed no more than three (3) 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 Livewire Steerable Diagnostic EP Catheters are as safe and effective as the predicate devices described herein.