DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 21, 2016

Innovative Health, LLC.
Rafal Chudzik
VP, R&D and Operations
1435 North Hayden Road
Suite 100
Scottsdale, Arizona 85257

Re: K162251
Trade/Device Name: Reprocessed Viking Diagnostic Electrophysiology Catheters
(*see list of models enclosed)*
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter, or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: November 16, 2016
Received: November 17, 2016

Dear Rafal Chudzik:

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. 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.

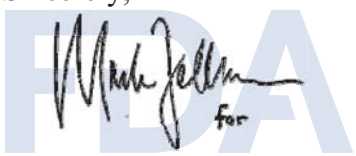
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



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

Enclosure

The item numbers included in the scope of this submission (K162251) are as follows:

Description	Item Number	Number of Electrodes	Electrode Spacing (mm)	Curve Type	French Size	Usable Length (cm)
Viking Diagnostic EP Catheter	400039	2	10	Josephson	5	115
	400040	2	10	Cournand	5	115
	400037	2	10	Josephson	6	115
	400038	2	10	Cournand	6	115
	400041	4	2	Josephson	5	115
	400042	4	2	Cournand	5	115
	400044	4	5	Josephson	5	115
	400045	4	5	Cournand	5	115
	400050	4	10	Josephson	5	115
	400051	4	10	Cournand	5	115
	400047	4	2,5,2	Josephson	5	115
	400048	4	2,5,2	Cournand	5	115
	400001	4	2	Josephson	6	115
	400002	4	2	Cournand	6	115
	400004	4	5	Josephson	6	115
	400005	4	5	Cournand	6	115
	400007	4	2,5,2	Josephson	6	115
	400008	4	2,5,2	Cournand	6	115
	400010	4	10	Josephson	6	115
	400011	4	10	Cournand	6	115
	400056	6	5	Josephson	5	115
	400057	6	5	Cournand	5	115
	400053	6	2	Josephson	5	115
	400054	6	2	Cournand	5	115
	400059	6	2,5,2	Josephson	5	115
	400060	6	2,5,2	Cournand	5	115
	400062	6	10	Cournand	5	115
	400013	6	2	Josephson	6	115
	400014	6	2	Cournand	6	115
	400016	6	5	Josephson	6	115
	400017	6	5	Cournand	6	115
	400019	6	2,5,2	Josephson	6	115
	400020	6	2,5,2	Cournand	6	115
	400022	6	10	Cournand	6	115
	400063	8	2	Josephson	5	115
	400064	8	2	Cournand	5	115
	400066	8	5	Cournand	5	115

The item numbers included in the scope of this submission (K162251) are as follows:

Description	Item Number	Number of Electrodes	Electrode Spacing (mm)	Curve Type	French Size	Usable Length (cm)
	400067	8	2,5,2	Josephson	5	115
	400068	8	2,5,2	Cournand	5	115
	400023	8	2	Josephson	6	115
	400024	8	2	Cournand	6	115
	400026	8	5	Cournand	6	115
	400027	8	2,5,2	Josephson	6	115
	400028	8	2,5,2	Cournand	6	115
	400070	10	2	Josephson	5	115
	400071	10	2	Cournand	5	115
	400072	10	5	Cournand	5	115
	400073	10	5	Josephson	5	115
	400074	10	2,5,2	Josephson	5	115
	400075	10	2,5,2	Cournand	5	115
	400104	10	5,5,5,20,5,5,5,5,5	Josephson	5	115
	400030	10	2	Josephson	6	115
	400031	10	2	Cournand	6	115
	400033	10	5	Cournand	6	115
	400034	10	2,5,2	Josephson	6	115
	400035	10	2,5,2	Cournand	6	115

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162251

Device Name
Reprocessed Viking Diagnostic Electrophysiology Catheter

Indications for Use *(Describe)*
The Reprocessed Viking Diagnostic Electrophysiology Catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

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:
Sharon Higgins
Sr. Quality Engineer
Innovative Health, LLC.
(480) 525-5970 (office)
(844) 965-9359 (fax)
snhiggins@innovative-health.com

Date prepared:
August 9, 2016

Device Information:

Trade/Proprietary Name:	Reprocessed Viking 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	Device	Manufacturer
K971265	Viking Diagnostic Electrode Catheter	C.R. Bard, Inc.

Device Description:

The Reprocessed Viking Diagnostic Electrophysiology Catheters are manufactured in various fixed curves and electrode spacing. The catheter has an insulated polymer shaft with platinum electrodes located along the distal section of the shaft.

Indications for Use:

The Reprocessed Viking Diagnostic Electrophysiology Catheters are intended for temporary intracardiac sensing, recording, stimulation and temporary pacing during the evaluation of cardiac arrhythmias.

Technological Characteristics:

The purpose, design, materials, function, and intended use of the Reprocessed Viking 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 Viking 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 Viking Diagnostic EP Catheters 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 Viking Diagnostic EP Catheters are as safe and effective as the predicate devices described herein.

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

Description	Item Number	Number of Electrodes	Electrode Spacing (mm)	Curve Type	French Size	Usable Length (cm)
Viking Diagnostic EP Catheter	400039	2	10	Josephson	5	115
	400040	2	10	Cournand	5	115
	400037	2	10	Josephson	6	115
	400038	2	10	Cournand	6	115
	400041	4	2	Josephson	5	115
	400042	4	2	Cournand	5	115
	400044	4	5	Josephson	5	115
	400045	4	5	Cournand	5	115
	400050	4	10	Josephson	5	115
	400051	4	10	Cournand	5	115
	400047	4	2,5,2	Josephson	5	115
	400048	4	2,5,2	Cournand	5	115
	400001	4	2	Josephson	6	115
	400002	4	2	Cournand	6	115
	400004	4	5	Josephson	6	115
	400005	4	5	Cournand	6	115
	400007	4	2,5,2	Josephson	6	115
	400008	4	2,5,2	Cournand	6	115
	400010	4	10	Josephson	6	115
	400011	4	10	Cournand	6	115
	400056	6	5	Josephson	5	115
	400057	6	5	Cournand	5	115
	400053	6	2	Josephson	5	115
	400054	6	2	Cournand	5	115
	400059	6	2,5,2	Josephson	5	115
	400060	6	2,5,2	Cournand	5	115
	400062	6	10	Cournand	5	115
	400013	6	2	Josephson	6	115
	400014	6	2	Cournand	6	115
	400016	6	5	Josephson	6	115
	400017	6	5	Cournand	6	115
	400019	6	2,5,2	Josephson	6	115
	400020	6	2,5,2	Cournand	6	115
	400022	6	10	Cournand	6	115
	400063	8	2	Josephson	5	115
	400064	8	2	Cournand	5	115
	400066	8	5	Cournand	5	115
	400067	8	2,5,2	Josephson	5	115

Description	Item Number	Number of Electrodes	Electrode Spacing (mm)	Curve Type	French Size	Usable Length (cm)
	400068	8	2,5,2	Cournand	5	115
	400023	8	2	Josephson	6	115
	400024	8	2	Cournand	6	115
	400026	8	5	Cournand	6	115
	400027	8	2,5,2	Josephson	6	115
	400028	8	2,5,2	Cournand	6	115
	400070	10	2	Josephson	5	115
	400071	10	2	Cournand	5	115
	400072	10	5	Cournand	5	115
	400073	10	5	Josephson	5	115
	400074	10	2,5,2	Josephson	5	115
	400075	10	2,5,2	Cournand	5	115
	400104	10	5,5,5,20,5,5,5,5,5	Josephson	5	115
	400030	10	2	Josephson	6	115
	400031	10	2	Cournand	6	115
	400033	10	5	Cournand	6	115
	400034	10	2,5,2	Josephson	6	115
	400035	10	2,5,2	Cournand	6	115

Table 5.1: Item Numbers