June 25, 2019

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

Re: K190785
Trade/Device Name: Reprocessed PentaRay Nav eco High-Density Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLG
Dated: March 26, 2019
Received: March 27, 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	Usable Length (cm)	French Size (Fr)	Curve	Electrode Spacing	Number of Electrodes
D128207	115	7	F	4-4-4	20
D128208	115	7	F	2-6-2	20
D128210	115	7	D	4-4-4	20
D128211	115	7	D	2-6-2	20

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)*
K190785

Device Name
Reprocessed PentaRay Nav eco High-Density Mapping Catheter

Indications for Use *(Describe)*
The Reprocessed PentaRay Nav eco High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e. recording or stimulation only. The catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

The catheter provides location information when used with the compatible Carto 3 EP Navigation Systems. (This catheter is not compatible with Carto 3 EP Navigation Systems prior to Version 3.x.)

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.
(480) 525-5911 (office)
(888) 965-7705 (fax)
ababcock@innovative-health.com

Date prepared:
March 26, 2019

Device Information:

Trade/Proprietary Name:	Reprocessed PentaRay Nav eco High-Density Mapping Catheter
Common or Usual Name:	Diagnostic Electrophysiology Mapping Catheter
Classification Name:	Electrode Recording Catheter or Electrode Recording Probe
Classification Number:	Class II, 21 CFR 870.1220
Product Code:	NLG

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K123837	PentaRay NAV eco High-Density Mapping Catheter	Biosense Webster, Inc.

Device Description:
The Reprocessed PentaRay Nav eco High-Density Mapping Catheter is designed to facilitate electrophysiological mapping of the heart with the Carto 3 EP Navigation System. It is designed for deployment in a heart chamber through an 8 F guiding sheath. This deflectable catheter consists of multiple 3F spines on its distal tip, each spine having multiple platinum electrodes that are used for stimulation and recording. A magnetic location sensor embedded in the deflectable tip transmits location information to the Carto 3 EP Navigation System. The catheter has two electrodes on the deflectable tip to provide for visualization of the tip when used with the Carto 3 EP Navigation System. Pushing forward on the catheter thumb knob deflects the tip; pulling back on the thumb knob straightens the tip. This device includes an irrigation lumen for connection to a source of continuous anticoagulant fluid.

This catheter interfaces with standard recording equipment and the Carto 3 EP Navigation System via interface cables with the appropriate connectors. Please consult the manufacturer for the appropriate interface cables.

For use in mapping procedures, refer to the instructions for the Carto 3 EP Navigation System.

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

Item Number	Description	Usable Length (cm)	French Size	Curve	Spacing (mm)	Electrodes
D128207	PentaRay Nav eco High-Density Mapping Catheter	115	7F	F	4-4-4	20
D128208	PentaRay Nav eco High-Density Mapping Catheter	115	7F	F	2-6-2	20
D128210	PentaRay Nav eco High-Density Mapping Catheter	115	7F	D	4-4-4	20
D128211	PentaRay Nav eco High-Density Mapping Catheter	115	7F	D	2-6-2	20

Table 5.1: Device Scope

Indications for Use:
The Reprocessed PentaRay NAV eco High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e. recording or stimulation only. The catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart.

The catheter provides location information when used with the compatible Carto 3 EP Navigation Systems. (This catheter is not compatible with Carto 3 EP Navigation Systems prior to Version 3.x).

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed PentaRay Nav eco High-Density Mapping 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 PentaRay Nav eco High-Density Mapping Catheter. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional testing
    - Visual Inspection
    - Dimensional Verification
    - Electrical Continuity and Resistance
    - Simulated Use
    - Leak/Occlusion
    - Inner lumen occlusion
    - Mechanical Characteristics
- Electrical Safety Testing
    - Dielectric and Current Leakage
- Packaging Validation

The Reprocessed Reprocessed PentaRay Nav eco High-Density Mapping 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 PentaRay Nav eco High-Density Mapping Catheter is as safe and effective as the predicate devices described herein.