November 3, 2017

Innovative Health, LLC.
Amy Stoklas-Oakes
Sr. Quality and Regulatory Manager
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K171788
Trade/Device Name: Reprocessed Halo XP Diagnostic Electrophysiology Catheters
(See Enclosed Model List)
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: September 25, 2017
Received: September 26, 2017

Dear Amy Stoklas-Oakes:

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 (DICE) 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 (DICE) 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,

for 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 are as follows:

Description	Item Number	Size (French)	Curve	Number of Electrodes	Spacing (mm)	Length (cm)
Halo XP Diagnostic EP Catheter	116008RT	7	Tricuspid	20	2-18-2-8-2	110
	D7T20282RT	7	Tricuspid	20	(20)-2-8-2	110
	D7T20P15RT	7	Tricuspid	20	2-13-2	110

Table 1: Devices in Scope

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)*

K171788

Device Name
Reprocessed Halo XP Diagnostic Electrophysiology (EP) Catheters

Indications for Use *(Describe)*
The Reprocessed Halo XP Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures, i.e. stimulation and recording only. The catheters' preformed halo shape of the tip section is designed specifically for the tricuspid annulus.

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
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Office of Chief Information Officer
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"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:
Amy Stoklas-Oakes
Innovative Health, LLC.
Sr. Quality and Regulatory Manager
(480) 525-5972 (office)
(888) 965-7705 (fax)
astoklas-oakes@innovative-health.com

Date prepared:
June 14, 2017

Device Information:

Trade/Proprietary Name:	Reprocessed Halo XP 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) Title	Manufacturer
K953768	Cordis Webster A20 Diagnostic Deflectable Tip Catheter	Cordis Webster, Inc., Biosense Webster
K953663	Cordis Webster T20 Diagnostic Deflectable Tip Catheter	Cordis Webster, Inc., Biosense Webster

Device Description:

The Reprocessed Deflectable Tip Halo XP Diagnostic Electrophysiology (EP) Catheters have been designed for electrophysiological mapping of the heart, in particular, the tricuspid annulus. The catheters have a high-torque shaft with a halo-shaped tip section containing ten pairs of platinum electrodes that can easily be seen under fluoroscopy. The tip section also contains a radiopaque mark in the center of the electrode array. The halo-shaped tip section has a preformed curve which can be positioned around the atrial aspect of the tricuspid annulus. The catheters facilitate simultaneous local electrograms spanning the tricuspid annulus, from the midseptal to anterior to lateral to posterolateral. Recordings of the entire annulus can be obtained without repositioning the catheter tip.

A piston in the handpiece is attached to an internal puller wire which changes the radius of curvature. When the piston is pushed forward, the radius of curvature of the

preformed loop is reduced; when the thumbknob is pulled back, the radius of the curvature is increased until the tip section returns to the preformed shape. The high torque shaft allows the plane of the curve to be maneuvered in order to facilitate accurate positioning.

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

Description	Item Number	Size (French)	Curve	Number of Electrodes	Spacing (mm)	Length (cm)
Halo XP Diagnostic EP Catheter	116008RT	7	Tricuspid	20	2-18-2-8-2	110
	D7T20282RT	7	Tricuspid	20	(20)-2-8-2	110
	D7T20P15RT	7	Tricuspid	20	2-13-2	110

Table 5.1: Item Numbers

Indications for Use:

The Reprocessed Halo XP Diagnostic EP Catheter is indicated for electrophysiological mapping of cardiac structures, i.e. stimulation and recording only. The catheters' preformed halo shape of the tip section is designed specifically for the tricuspid annulus.

Technological Characteristics:

The purpose, design, materials, function, and intended use of the Halo XP Diagnostic 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 Halo XP Diagnostic EP Catheters.

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 Halo XP 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 Halo XP Diagnostic EP Catheters are as safe and effective as the predicate devices described herein.