DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 14, 2016

Innovative Health, LLC
Rafal Chudzik
Director of Engineering
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K153153
Trade/Device Name: Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: February 5, 2016
Received: February 8, 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.

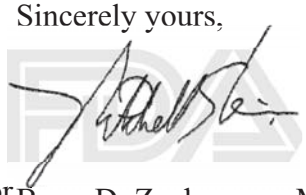
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 yours,



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

Enclosure

Reprocessed Single-Use Device Models Included in Clearance:

Description	Item Number	Number of Electrodes	Electrode Spacing (mm)	Loop Diameter or Curve (mm)	French Size	Length (cm)
Lasso Nav *eco* Fixed Diagnostic EP Catheter	D134901	10	4.5	15	7	115
	D134902	20	4.5 pairs	15	7	115
	D134903	10	6.0	20	7	115
	D134904	20	6.0 pairs	20	7	115
	D134905	10	8.0	25	7	115
	D134906	20	8.0 pairs	25	7	115
Lasso 2515 Nav *eco* Variable Diagnostic EP Catheter	D134301	20	2-6-2	25–15	7	115
	D134302	10	8.0	25–15	7	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)*

K153153

Device Name
Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheter

Indications for Use *(Describe)*
The Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Catheters are indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The Reprocessed LASSO NAV eco and Reprocessed LASSO 2515 NAV eco Variable Catheters are designed to obtain electrograms in the atrial regions of the heart.

The Reprocessed LASSO NAV and Reprocessed LASSO 2515 NAV eco Variable Catheters provide location information when used with compatible CARTO 3 EP Navigation Systems. (These catheters are not compatible with CARTO 3 EP Navigation Systems prior to Version 2.3.)

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:
Rafal Chudzik
Director of Engineering
(602) 326-7716 (cell)
(480) 525-6006 (office)
(844) 965-9359 (fax)
rchudzik@innovative-health.com

Date prepared:
October 30, 2015

Device Information:

Trade/Proprietary Name:	Reprocessed LASSO® NAV eco and LASSO 2515 NAV eco Variable Electrophysiology (EP) Catheter
Common Name:	Electrophysiological Mapping 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
K113213	LASSO® 2515 NAV *eco* Variable Catheter and LASSO® NAV *eco* Catheter	Biosense Webster
K093376	LASSO® NAV Catheter	Biosense Webster
K081258	Variable LASSO® NAV Catheter, Models: D-1290-01, D-1290-2	Biosense Webster

Reference Device:

510(k) Number	510(k) Title	Reprocessor
K112292	Reprocessed 2515 NAV Variable Electrophysiology Catheter	Stryker Sustainability Solutions

Device Description:

Reprocessed LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* Catheter

The Reprocessed LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* Catheter have been designed to facilitate electrophysiological mapping of the atria of the heart with the CARTO 3 EP Navigation System and a reference device. Both catheters are deployed in the right or left atrium through an 8F guiding sheath. Both deflectable catheters consists of a 4.5 F (Lasso NAV eco) or 4 F (LASSO NAV eco Variable) circular spine on the distal tip, with platinum/iridium electrodes that can be used for stimulation and recording.

The Reprocessed LASSO 2515 NAV *eco* Variable Catheter features a Nitinol loop design that allows the expansion and contraction of the loop to custom-fit veins with different sizes, ranging from 25mm to 15mm diameter (± 15%).

The Reprocessed LASSO NAV *eco* Catheter is a fixed catheter with three fixed catheter sizes, namely 15, 20, 25 mm loop sizes to accommodate different vein sizes. Each loop size will be available with either 10 or 20 electrodes.

Indications for Use:

Reprocessed LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* Catheter

The Reprocessed LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* Catheter are indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. These catheters are designed to obtain electrograms in the atrial regions of the heart.

The Reprocessed LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* Catheter provide location information when used with compatible CARTO EP Navigation Systems. (These catheters are not compatible with CARTO 3 EP Navigation Systems prior to Version 2.3).

> **Note:** Only the catheter is the subject of this submission. Any other related equipment is not included in the scope of this submission.

Technological Characteristics:

The purpose, design, materials, function, and intended use of the Reprocessed LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* Catheter 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 LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* Catheter. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional Testing
  - Visual Inspection
  - Dimensional Verification
  - Electrical Performance
  - Simulated Use
  - Mechanical Characteristics
- Electrical Safety Testing
  - Dielectric and Current Leakage
- Packaging Validation

The Reprocessed LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* 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 LASSO 2515 NAV *eco* Variable Catheter and Reprocessed LASSO NAV *eco* Catheter are as safe and effective as the predicate devices described herein.