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

July 12, 2017

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

Re: K163560
Trade/Device Name: Reprocessed AcuNav Diagnostic Ultrasound Catheter (*see Enclosed Model List)*
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: July 7, 2017
Received: July 10, 2017

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,

for

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

Enclosure

Table 1: K163560 List of Models in Scope

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

Item Number	Description	Sheath Usable Length (cm)	French Size	System Compatibility
10135936	AcuNav Diagnostic Ultrasound Catheter	90	8F	Acuson/Siemens
10135910	AcuNav Diagnostic Ultrasound Catheter	90	8F	GE Vivid i & Vivid q Ultrasound System

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)*

K163560

Device Name
Reprocessed AcuNav Diagnostic Ultrasound Catheter

Indications for Use *(Describe)*
The Reprocessed Acunav Diagnostic Ultrasound Catheter is intended for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult patients.

The reprocessed device is not indicated for use with pediatric patients.

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:
Rafal Chudzik
Innovative Health, LLC.
VP, R&D and Operations
(480) 525-6006 (office)
(844) 965-9359 (fax)
rchudzik@innovative-health.com

Date prepared:
December 16, 2016

Device Information:

Trade/Proprietary Name:	Reprocessed AcuNav Diagnostic Ultrasound Catheters
Common Name:	Diagnostic Ultrasound Catheters
Classification Name:	Reprocessed Intravascular Ultrasound Catheter
Classification Number:	Class II, 21 CFR 870.1200
Product Code:	OWQ

Predicate Device:

510(k) Number	510(k) Title	Manufacturer
K153090	Reprocessed AcuNav Diagnostic Ultrasound Catheters	Innovative Health, LLC.
K071234	AcuNav Diagnostic Ultrasound Catheter 8F and 10F	Siemens Medical Solutions

Device Description:

The Reprocessed AcuNav Diagnostic Ultrasound Catheters distal end has an ultrasound transducer providing 2-D imaging. A steering mechanism controls the image plane orientation through four-way articulation of the tip.

Item Number	Description	Sheath Usable Length (cm)	French Size	System Compatibility
10135936	AcuNav Diagnostic Ultrasound Catheter	90	8F	Acuson/Siemens
10135910	AcuNav Diagnostic Ultrasound Catheter	90	8F	GE Vivid i & Vivid q Ultrasound System

Table 5.1: Device Scope

Indications for Use:

The Reprocessed AcuNav Diagnostic Ultrasound Catheter is intended for intracardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the hearts of adult patients.

The reprocessed device is not indicated for use with pediatric patients.

Technological Characteristics:

The purpose, design, materials, function, and intended use of the Reprocessed Diagnostic Ultrasound Catheters are identical to the predicate devices. There are no changes to the claims, clinical applications, performance specifications, or method of operation. In addition, Innovative Health's reprocessing of the Diagnostic Ultrasound 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 Diagnostic Ultrasound Catheters. This included the following:

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

The Reprocessed Diagnostic Ultrasound Catheters are reprocessed no more than three (3) times. 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 Diagnostic Ultrasound Catheter is as safe and effective as the predicate devices described herein.