DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

June 2, 2017

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

Re: K170311
Trade/Device Name: Reprocessed Agilis NxT Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Reprocessed Catheter Introducer
Regulatory Class: Class II
Product Code: PNE
Dated: April 28, 2017
Received: May 1, 2017

Dear Ms. 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 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 Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment

The following models are included in the clearance of K170311:

- 408309
- 408310
- G408324
- G408318
- G408319

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)*
K170311

Device Name
Reprocessed Agilis NxT Steerable Introducer

Indications for Use *(Describe)*
The Reprocessed Agilis NxT Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart including the left side of the heart through the interatrial septum.

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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"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:
January 31, 2017

Device Information:

Trade/Proprietary Name:	Reprocessed Agilis NxT Steerable Introducer
Common Name:	Steerable Introducer
Classification Name:	Reprocessed Catheter Introducer
Classification Number:	Class II, 21 CFR 870.1340
Product Code:	PNE

Predicate Device:

510(k) Number	Device	Manufacturer
K081645	Agilis NxT Steerable Introducer	St. Jude Medical
K061363	Agilis NxT Steerable Introducer	St. Jude Medical

Device Description:

The reprocessed Agilis NxT steerable introducer consists of a steerable sheath, dilator, and guidewire which is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling and pressure monitoring. The handle is equipped with a rotating collar to deflect the tip clockwise ≥ 180° and counterclockwise ≥ 90°. The steerable introducer features distal vent holes to facilitate aspiration and minimize cavitation and a radiopaque tip marker to improve fluoroscopic visualization.

Note: Only the steerable sheath and dilator are subject of this submission. The guidewire is purchased off-the shelf (K935170) and packaged with the reprocessed devices.

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

DESCRIPTION	ITEM NUMBER	FRENCH SIZE		USEABLE LENGTH (cm)	CURVE TYPE	CURVE REACH (mm)
		ID	OD			
AGILIS NxT STEERABLE INTRODUCER	408309	8.5F	11.5F	71	SMALL CURL DUAL REACH BI-DIRECTIONAL	16.8
AGILIS NxT STEERABLE INTRODUCER	408310	8.5F	11.5F	71	MEDIUM CURL DUAL REACH BI-DIRECTIONAL	22.4
AGILIS NxT STEERABLE INTRODUCER	G408324	8.5F	11.5F	71	LARGE CURL DUAL REACH BI-DIRECTIONAL	50.0
AGILIS NxT STEERABLE INTRODUCER	G408318	8.5F	11.5F	61	SMALL CURL DUAL REACH BI-DIRECTIONAL	16.8
AGILIS NxT STEERABLE INTRODUCER	G408319	8.5F	11.5F	61	MEDIUM CURL DUAL REACH BI-DIRECTIONAL	22.4

Table 5.1: Item Numbers

Indications for Use:

The Reprocessed Agilis NxT Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart including the left side of the heart through the interatrial septum.

Technological Characteristics:

The purpose, design, materials, function, and intended use of the Reprocessed Steerable Introducer 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 Agilis NxT Steerable Introducer. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Physical and Mechanical Testing
    - Visual Inspection
    - Dimensional Verification
    - Tensile
    - Deflection
    - Simulated Use
    - Leak
    - Radiopacity
- Packaging Validation

The Reprocessed Agilis NxT Steerable Introducer 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 Agilis NxT Steerable Introducers are as safe and effective as the predicate devices described herein.