August 7, 2023

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

Re: K230376
Trade/Device Name: Reprocessed Agilis NxT Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: PNE
Dated: July 14, 2023
Received: July 17, 2023

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,

Rachel E. Neubrander -S

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Reprocessed Agilis NxT Steerable Introducer

Indications for Use *(Describe)*
The Reprocessed Agilis NxT 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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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
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Contact Name and Information:
Amanda Babcock
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ababcock@innovative-health.com

Date prepared:
2/10/2023

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	Abbott (formerly St. Jude Medical)

Reference Device:

510(k) Number	Device	Manufacturer
K170311	Reprocessed Agilis NxT Steerable Introducer	Innovative Health, LLC

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 the 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			
Reprocessed Agilis Nxt Steerable Introducer	408309	8.5F	11.5F	71	Small Curl Dual Reach Bi-Directional	16.8
Reprocessed Agilis Nxt Steerable Introducer	408310	8.5F	11.5F	71	Medium Curl Dual Reach Bi-Directional	22.4
Reprocessed Agilis Nxt Steerable Introducer	G408324	8.5F	11.5F	71	Large Curl Dual Reach Bi-Directional	50.0
Reprocessed Agilis Nxt Steerable Introducer	G408318	8.5F	11.5F	61	Small Curl Dual Reach Bi-Directional	16.8
Reprocessed Agilis Nxt Steerable Introducer	G408319	8.5F	11.5F	61	Medium Curl Dual Reach Bi-Directional	22.4
Reprocessed Agilis Nxt Steerable Introducer	G408320	8.5F	11.5F	71	Small Curl Dual Reach Bi-Directional	16.8
Reprocessed Agilis Nxt Steerable Introducer	G408321	8.5F	11.5F	71	Medium Curl Dual Reach Bi-Directional	22.4

Table 5.1: Device Scope

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 device. 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 Testing
  - Deflection Testing
  - Simulated Use Testing
  - Leak Testing
  - Radiopacity Testing
- Packaging Validation

The Reprocessed Agilis NxT Steerable Introducer is reprocessed no more than one (1) time. Each device is marked, serialized 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 Introducer, is as safe and effective as the predicate device described herein.