April 4, 2024

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

Re: K232037
Trade/Device Name: Reprocessed VersaCross Steerable Sheath; Reprocessed SureFlex Steerable Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Reprocessed Catheter Introducer
Regulatory Class: Class II
Product Code: PNE
Dated: February 20, 2024
Received: February 20, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Julie B. Mackel -S

For

Katherine Trivedi

Acting 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

The Reprocessed Device Models in scope of K232037 are as follows:

Product Description	Item Number	Sheath French Size	Sheath Length	Sheath Curve	Bidirectional Curve Angle	Dilator French Size	Dilator Length	Dilator Curve
Reprocessed VersaCross Steerable Sheath	VST85-35-BD-71S-D0	8.5F	72 cm	S	90° CCW/ 180°CW	8.5F	95 cm	D0
	VST85-35-BD-71S-D1			S				D1
	VST85-35-BD-71M-D0			M				D0
	VST85-35-BD-71M-D1			M				D1
	VST85-35-BD-71L-D0			L				D0
	VST85-35-BD-71L-D1			L				D1

Product Description	Item Number	Sheath French Size	Sheath Length	Sheath Curve	Bidirectional Curve Angle	Dilator French Size	Dilator Length	Dilator Curve
Reprocessed SureFlex Steerable Guiding Sheath	TSK85-32-BD-71S	8.5F	71 cm	S	90° CCW/ 180°CW	8.5F	94 cm	N/A
	TSK85-32-BD-71M			M				N/A
	TSK85-32-BD-71L			L				N/A

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)*

K232037

Device Name
Reprocessed VersaCross Steerable Sheath and Reprocessed SureFlex Steerable Guiding Sheath

Indications for Use *(Describe)*
The Reprocessed VersaCross Steerable Sheath is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

The Reprocessed SureFlex Steerable Guiding Sheath is indicated for introducing various cardiovascular catheters to 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.

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510(k) SUMMARY

As required by 21 CFR 807.92

Submitter's Name and Address:
Innovative Health, LLC.
1435 N. Hayden Road, Suite 100
Scottsdale, AZ 85257

Contact Name and Information:
Amanda Babcock
Regulatory Affairs Manager
Innovative Health, LLC.
(480) 525-5911 (office)
(888) 965-7706 (fax)
ababcock@innovative-health.com

Date prepared:
July 7, 2023

Device Information:

Trade/Proprietary Name:	Reprocessed VersaCross Steerable Sheath and SureFlex Steerable Guiding Sheath
Common Name:	Steerable/Guiding Sheath
Classification Name:	Reprocessed Catheter Introducer
Classification Number:	Class II, 21 CFR 870.1340
Product Code:	PNE

Predicate Device:

510(k) Number	510(k) Device	Manufacturer
K190688	VersaCross Steerable Sheath VersaCross Transseptal Dilator	Baylis Medical Company, Inc.

Additional Predicate Device:

510(k) Number	510(k) Device	Manufacturer
K122926	SureFlex Steerable Guiding Sheath Kit	Baylis Medical Company Inc.

Reference Device:

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

Device Description:
Reprocessed VersaCross Steerable Sheath

The Reprocessed VersaCross Steerable Sheath consists of three components: a Reprocessed VersaCross Steerable Sheath, a Reprocessed VersaCross Transseptal Dilator, and a 0.035" J-tipped mechanical guidewire.

The Reprocessed VersaCross Steerable Sheath is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The sheath provides superior torque control and is flexible. The Reprocessed VersaCross Transseptal Dilator provides support for the sheath, features a tapered tip and a shaft that can be reshaped manually. Radiopaque tips maximize visualization of the sheath the dilator during manipulation.

The J-tipped Guidewire, hereafter referred to as the "guidewire", comprises a stainless-steel core with a flexible, spiral shaped PTFE coated steel coil along the full length of the device. The guidewire is coated in its entirety with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for this coating.

Reprocessed Sureflex Steerable Sheath
The Reprocessed SureFlex Steerable Guiding Sheath consists of three components: a reprocessed sheath, a reprocessed dilator and a J-tipped Mechanical Guidewire.

The Reprocessed SureFlex Steerable Sheath is designed for safe and easy catheterization and angiography of specific heart chambers and locations. The sheath provides superior torque control and is flexible. The radiopaque tip maximizes visualization of the sheath during manipulation. The dilator provides support for the sheath and has a tapered tip.

The J-tipped Guidewire, hereafter referred to as the "guidewire", comprises a stainless-steel core with a flexible, spiral shaped PTFE coated steel coil along the full length of the device. The guidewire is coated in its entirety with a hydrophobic lubricious coating for smoother device manipulation. No pre-conditioning is required for this coating.

Note: Only the steerable sheaths and dilator are subject of this submission. The guidewires are purchased off-the shelf and packaged with the reprocessed devices.

Indications for Use:
The Reprocessed VersaCross Steerable Sheath is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

The Reprocessed SureFlex Steerable Guiding Sheath is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum.

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

Product Description	Item Number	Sheath French Size	Sheath Length	Sheath Curve	Bidirectional Curve Angle	Dilator French Size	Dilator Length	Dilator Curve
Reprocessed VersaCross Steerable Sheath	VST85-35-BD-71S-D0	8.5F	72 cm	S	90° CCW/ 180°CW	8.5F	95 cm	D0
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	VST85-35-BD-71M-D0			M				D0
	VST85-35-BD-71M-D1			M				D1
	VST85-35-BD-71L-D0			L				D0
	VST85-35-BD-71L-D1			L				D1
Reprocessed SureFlex Steerable Guiding Sheath	TSK85-32-BD-71S	8.5F	71 cm	S	90° CCW/ 180°CW	8.5F	94 cm	N/A
	TSK85-32-BD-71M			M				N/A
	TSK85-32-BD-71L			L				N/A

Table 1: Device Scope

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed devices 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 evaluated substantial equivalence to the predicate devices. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional Testing
  - Visual Inspection
  - Dimensional Inspection
  - Tip Deflection
  - Tip Buckling
  - Valve/Joint leak
  - Radiopacity
  - Simulated Use
  - Torque Testing
  - Tensile Testing
  - Corrosion Testing
- Packaging Validation

The Reprocessed Steerable Sheaths are 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 testing evaluated substantial equivalence to the predicate devices described herein.