July 22, 2020

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

Re: K192998
Trade/Device Name: Reprocessed BRK Transseptal Needle
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar, Reprocessed
Regulatory Class: Class II
Product Code: NMK
Dated: June 12, 2020
Received: June 15, 2020

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,

for 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

The model numbers in the scope of this clearance are as follows.

- BRK Transseptal Needle Model Numbers 407200, 407201, 407205, G407215, 407206, 407207
- BRK XS Transseptal Needle Model Numbers G407208, G407209, G407210, G407216, G407211, G407212

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192998

Device Name
Reprocessed BRK Transseptal Needle

Indications for Use *(Describe)*
The Reprocessed BRK Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access.

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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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:
Amanda Babcock
Regulatory Affairs Manager
Innovative Health, LLC.
(480) 525-5911 (office)
(888) 965-7705 (fax)
ababcock@innovative-health.com

Date prepared:
July 22, 2020

Device Information:

Trade/Proprietary Name:	Reprocessed BRK Transseptal Needle
Common Name:	Transseptal Needle
Classification Name:	Trocar, reprocessed
Classification Number:	Class II, 21 CFR §870.1390
Product Code:	NMK

Predicate Device:

510(k) Number	510(k) Device	Manufacturer
K122587	BRK Transseptal Needle	St. Jude Medical
K072278	BRK Transseptal Needle	St. Jude Medical

Reference Device:

510(k) Number	510(k) Device	Manufacturer
K172950	TSN Transseptal Needle	Pressure Products Medical Device Manufacturing LLC

Device Description:
The reprocessed BRK Transseptal Needle consists of a luminal stainless steel needle and solid stainless steel stylet. The distal section of the needle is curved to facilitate positioning within the heart when used with a St. Jude Medical transseptal introducer set. Within this curved section, there is an abrupt step down in the outer diameter of the needle to mate with the internal diameter of the dilator of a St. Jude Medical transseptal introducer set. The distal tip of the needle is beveled to facilitate the puncture process. The proximal end of the needle is configured with a pointer flange (indicating distal curve orientation) and is fitted with a 2-way stopcock to provide needle lumen access for aspiration, fluid injection/infusion, blood sampling, pressure monitoring, and stylet and/or guidewire insertion (0.014" maximum guidewire diameter for an 18 gauge needle). The stylet is straight and isodiametric throughout its length. The proximal end of the stylet is fitted with a curved clip to lock onto the proximal needle hub when inserted into the needle lumen. The stylet is designed to facilitate needle advancement within

the dilator. The reprocessed needle is available in various useable lengths and distal curve configurations.

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

Description	Item Number	Needle Gauge Size	Bevel Angle	Curve Type	Max OD (mm)	Min ID (mm)	Usable Length (cm)
BRK Transseptal Needles	407200	18 ga	50°	BRK	1.3	0.50	71
	407201	18 ga	50°	BRK-1	1.3	0.50	71
	407205	18 ga	50°	BRK	1.3	0.50	89
	G407215	18 ga	50°	BRK-1	1.3	0.50	89
	407206	18 ga	50°	BRK	1.3	0.50	98
	407207	18 ga	50°	BRK-1	1.3	0.50	98
BRK XS Transseptal Needles	G407208	18 ga	30°	BRK XS	1.3	0.50	71
	G407209	18 ga	30°	BRK-1 XS	1.3	0.50	71
	G407210	18 ga	30°	BRK XS	1.3	0.50	89
	G407216	18 ga	30°	BRK-1 XS	1.3	0.50	89
	G407211	18 ga	30°	BRK XS	1.3	0.50	98
	G407212	18 ga	30°	BRK-1 XS	1.3	0.50	98

Indications for Use:
The Reprocessed BRK Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed BRK Transseptal Needle 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 this device 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 BRK Transseptal Needle. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional Testing
  - Visual Inspection
  - Dimensional Verification
  - Simulated Use
  - Leak Testing
  - Mechanical Characteristics
  - Corrosion Resistance
- Packaging Validation

The Reprocessed BRK Transseptal Needle is reprocessed no more than one (1) time. Each device is 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 BRK Transseptal Needle is as safe and effective as the predicate device described herein.