October 19, 2026

Innovative Health, LLC
Meerna Muradvich
Senior Regulatory Affairs Engineer
1435 N. Hayden Rd.
Suite 100
Scottsdale, Arizona 85257

Re: K262917
Trade/Device Name: Reprocessed BRK Transseptal Needle
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II
Product Code: NMK
Dated: August 19, 2026
Received: August 20, 2026

Dear Meerna Muradvich:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Katherine N. Trivedi -S

Digitally signed by Katherine N. Trivedi -S
Date: 2026.10.19 15:30:53 -06'00'

Katherine Trivedi
Assistant Director
DHT2B: Division of Circulatory Support, Structural, and Vascular Devices
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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)*
K262917

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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Date prepared:
August 19, 2026

Device Information:

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

Predicate Device:

510(k) Number	510(k) Device	Manufacturer
K192998	Reprocessed BRK Transseptal Needle	Innovative Health, LLC.
K122587	BRK Transseptal Needle	St. Jude Medical/Abbott
K072278	BRK Transseptal Needle	St. Jude Medical/Abbott

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 transseptal sheath set from Abbott Medical. 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 transseptal sheath set from Abbott Medical. 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 in. 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.

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.

The item numbers included in the 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)
Reprocessed 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
Reprocessed 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

Table 1: Item Numbers

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed BRK Transseptal Needle is 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 evaluated substantial equivalence to the predicate devices.

This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation

- Functional Testing
    - Needle Visual Inspection
    - Dimensional Verification
    - Simulated Use
    - Needle Valve/Joint Leak
    - Tensile Testing
    - Corrosion Resistance
- Packaging Validation

The Reprocessed BRK Transseptal Needle is reprocessed no more than three (3) times. 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.