July 30, 2020

Innovative Health, LLC.
Ms. Christina Fleming
VP, Quality and Regulatory Affairs
1435 North Hayden Road, Suite 100
Scottsdale, Arizona 85257

Re: K200060
Trade/Device Name: Reprocessed NRG Transseptal Needle
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy catheter, reprocessed
Regulatory Class: Class II
Product Code: QLZ
Dated: June 19, 2020
Received: June 22, 2020

Dear Christina Fleming:

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 Reprocessed NRG Transseptal Needle model numbers in the scope of this clearance are as follows: NRG-E-56-32-C0, NRG-E-HF-71-C0, NRG-E-HF-89-C0, NRG-E-HF-98-C0, NRG-E-HF-71-C1, NRG-E-HF-89-C1, NRG-E-HF-98-C1.

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)*
K200060

Device Name
Reprocessed NRG Transseptal Needle

Indications for Use *(Describe)*
The Reprocessed NRG Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

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(c)

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

Contact Name and Information:
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VP, Quality and Regulatory Affairs
Innovative Health, LLC.
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(888) 965-7705 (fax)
tfleming@innovative-health.com

Date prepared:
July 29, 2020

Device Information:

Trade/Proprietary Name:	Reprocessed NRG Transseptal Needle
Common Name:	Catheter, Septostomy
Classification Name:	Septostomy catheter, reprocessed
Classification Number:	Class II, 21 CFR §870.5175
Product Code:	QLZ

Predicate Device:

510(k) Number	510(k) Device	Manufacturer
K073326	NRG Transseptal Needle	Baylis Medical Company Inc.

Device Description:
The reprocessed NRG Transseptal Needle delivers radiofrequency (RF) power in a monopolar mode between its distal electrode and a commercially available Disposable Indifferent (Dispersive) Patch (DIP) Electrode. The NRG Transseptal Needle is loaded through a Transseptal Sheath/Dilator set and is connected at its proximal end to the BMC Radiofrequency Puncture Generator via the BMC Connector Cable and, optionally, to an external pressure monitoring system via a luer connection.

The distal end of the needle contains a hole to facilitate injection of contrast solution and the monitoring of cardiac pressures. The active tip is specially shaped to be atraumatic to the cardiac tissue unless RF energy is applied.

Note: Detailed information concerning the BMC Radiofrequency Puncture Generator is contained in a separate manual that accompanies the Generator (entitled "BMC Radiofrequency Puncture Generator Instructions for Use"). Please refer to the applicable user manual for recommended settings for the compatible generators.

Note: Only the reprocessed NRG Transseptal Needle is the subject of this submission. Any other related equipment is not included in the scope of this submission.

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

Description	Item Number	Curve Type	Shaft OD (mm)	Usable Length (cm)
NRG Transseptal Needle	NRG-E-56-32-C0	C0	19Ga/1.1mm	56
	NRG-E-HF-71-C0	C0	18Ga/1.3mm	71
	NRG-E-HF-89-C0	C0	18Ga/1.3mm	89
	NRG-E-HF-98-C0	C0	18Ga/1.3mm	98
	NRG-E-HF-71-C1	C1	18Ga/1.3mm	71
	NRG-E-HF-89-C1	C1	18Ga/1.3mm	89
	NRG-E-HF-98-C1	C1	18Ga/1.3mm	98

Indications for Use:
The Reprocessed NRG Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

Technological Characteristics:
The purpose, design, materials, function, and intended use of the Reprocessed NRG 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 were conducted to demonstrate performance of the Reprocessed NRG Transseptal Needle. This included the following:

- Biocompatibility
- Cleaning Validation
- Sterilization Validation
- Functional Testing
  - Visual Inspection
  - Dimensional Verification
  - Simulated Use
  - Electrical Continuity
  - Leak Testing
  - Corrosion Resistance
  - Mechanical Characteristics
- Electrical Safety Testing
  - Dielectric and Current Leakage
- Packaging Validation

The Reprocessed NRG 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 NRG Transseptal Needle is as safe and effective as the predicate device described herein.