October 7, 2022

Lake Region Medical
Deko Hussein
Sr. Regulatory Specialist
340 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K221575
Trade/Device Name: Pre-Formed Blue
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 9, 2022
Received: September 9, 2022

Dear Deko Hussein:

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 Jaime Raben
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)*
K221575

Device Name
Pre-Formed Blue

Indications for Use *(Describe)*
The Pre-Formed Blue guidewire is intended to facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used during transcatheter aortic valve procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K221575 510(k) Summary

Submitter Lake Region Medical
Address: 340 Lake Hazeltine Drive
Chaska, MN 55318

Establishment Registration Number: 2126666
Primary Contact Person: Deko Hussein, Sr. Regulatory Specialist
Email: deko.hussein@integer.net
Phone: (952) 641-8302
Date Prepared May 31, 2022

Subject Device

Name of Device (Trade): Pre-Formed Blue
Common or Usual Name: Catheter Guidewire
Classification: Catheter Guidewire (21 CFR 870.1330)
Regulatory Class: Class II
Product Code: DQX

Predicate Device

Device Name: Pre-Formed Guidewire
Manufacturer: Lake Region Medical
510(k) Number: K151244 (Cleared June 11, 2015)
Regulatory Class: Class II per 21 CFR 870.1330
Product Code: DQX

The identified predicate device, Pre-Formed guidewire (K151244), has not been subject to a design related recall or any recall since clearance. This Traditional 510K is submitted to modify the coating applied to the device from a green PTFE to blue PTFE for market differentiation purposes, this is the primary change to the device requiring the submission of a pre-market notification.

The Pre-Formed Blue guidewire is designed to facilitate device placement during TAVR procedures and has a unique pre-shaped spiral distal tip to ensure placement within the heart. The guidewire is intended for single use.

The guidewire has a 0.035" diameter and is 275cm in length. The guidewire composed of two primary components: a core, and a coil. Both components are made of stainless steel. The core wire component is a piece of stainless-steel wire which is ground on the distal end to fit into the coil and provide flexibility. The coil component is fitted over the distal end of the core and is a stainless-steel coiled wire coated with blue PTFE coating. The coil and core components are secured together using a weld on the distal end, forming the guidewire. The pre-shaped distal end of the guidewire is available in two sizes (extra-small and small).

The Pre-Formed Blue guidewire is sterilized using ethylene oxide. There are no accessories packaged with the Pre-Formed Blue guidewire.

Indications for Use:

Pre-Formed Blue guidewire is intended to facilitate the introduction and placement of interventional devices within the chambers of the heart, including those used during transcatheter aortic valve procedures.

Comparison of Technological Characteristics with the Predicate Devices

The Pre-Formed Blue is substantially equivalent to the selected predicate. The Pre-Formed Blue has the same indication for use/intended use and principles of operation as the legally marketed Pre-Formed guidewire (K151244). The functional characteristics of the Pre-Formed Blue guidewire are substantially equivalent to the Pre-Formed guidewire with regards to material, dimensions and method of construction. The design modifications to the new device (Pre-Formed Blue) include differences in the PTFE color used to coat the device and dimensional changes to the distal spiral to meet customer requirements. Performance and safety testing have shown that these modifications have not raised any new questions of safety or efficacy and the device continues to meet its intended use.

Summary of Testing

The determination of substantial equivalence includes an assessment of non-clinical (bench) performance testing. This testing was performed in order to demonstrate that the Pre-Formed Blue guidewire met applicable design and performance requirements and to support a determination of substantial equivalence. The following testing was conducted, according to established procedures, and samples were analyzed according to predetermined acceptance criteria utilized by the predicate device, Pre-Formed. In addition, FDA guidance *Coronary, Peripheral and Neurovascular Guidewires Performance Tests and Recommended Labeling (October 10, 2019)* was utilized to support demonstrating substantial equivalence.

- **Thermal Conditional and Packaging Distribution** - Tested in accordance with ASTM D4169 (Distribution simulation) and ISTA 2A (environmental conditioning). The predetermined acceptance criteria were met.
- **FDA Preconditioning** – Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Visual Inspection** – Tested in accordance with EN ISO 11070 & FDA Guidance. The predetermined acceptance criteria were met.
- **Pouch Peel Tear** - Tested in accordance with ASTM F88-15. The predetermined acceptance criteria were met.
- **Seal Integrity** – Tested in accordance with ASTM F1929-15. The predetermined acceptance criteria were met.
- **Bubble Leak Testing** – Tested in accordance with ASTM F2096-11(2019). The predetermined acceptance criteria were met.
- **Dimensional – Length, Outer Diameter** – Tested in accordance with EN ISO 11070 & FDA Guidance. The predetermined acceptance criteria were met.
- **Dimensional – Curve** – Tested in accordance with internal procedures. The predetermined acceptance criteria were met.
- **Lubricity** - Tested in accordance with FDA Guidance. The predetermined acceptance criteria were met.
- **Guidewire Distal & Proximal Joint Pull Test** - Tested in accordance with EN ISO 11070 & FDA Guidance. The predetermined acceptance criteria were met.
- **3 Point Bend** - Tested in accordance with internal procedures. The predetermined acceptance criteria were met.

- **Coating Adhesion** – Tested in accordance with FDA Guidance. The predetermined acceptance criteria were met.
- **Radiopacity** - Tested in accordance with EN ISO 11070 & FDA Guidance. The predetermined acceptance criteria were met.
- **ISO Corrosion Test** - Tested in accordance with EN ISO 11070 & FDA Guidance. The predetermined acceptance criteria were met.
- **Particulate Residue Test** - Tested in accordance with FDA Guidance. The predetermined acceptance criteria were met.
- **ISO Fracture Test** - Tested in accordance with EN ISO 11070. The predetermined acceptance criteria were met.
- **ISO Flex Test** - Tested in accordance with EN ISO 11070. The predetermined acceptance criteria were met.
- **Torque Fatigue** - Tested in accordance with FDA Guidance. The predetermined acceptance criteria were met.
- **Kink Resistance** – Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Tip Shape Retention** – Tested in accordance with internal procedures. The predetermined acceptance criteria were met.
- **Spiral (Tip) Compression** – Tested in accordance with internal procedures. The predetermined acceptance criteria were met.
- **Biocompatibility** – Tested in accordance with ISO 10993-1 and all applicable parts of this standard series. The predetermined acceptance criteria were met.

Performance Data (Animal)

Testing was performed in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory studies. The subject device Pre-Formed Blue guidewire shares the same intended use and fundamental scientific technology as the predicate and demonstrated all safety and performance objectives as the device performed equivalent to the predicate, Pre-Formed guidewire, and demonstrated all Customer Requirement Specifications as measured by post procedure feedback forms.

Conclusion: The Pre-Formed Blue guidewire, described in this submission, met all design input requirements based on the intended use. The results of these tests support a determination of substantial equivalence to the predicate device, the Pre-Formed Guidewire (K151244).