Lake Region Medical
Clara Lee
Sr. Regulatory Affairs Specialist
340 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K242824
Trade/Device Name: PTFE Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 18, 2024
Received: November 6, 2024

Dear Clara Lee:

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.

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,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242824

Device Name

PTFE Guidewire

Indications for Use *(Describe)*

To facilitate the placement of devices for diagnostic and interventional procedures. These guidewires are not intended for PTCA use.

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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Lake Region MEDICAL
An Integer company

PTFE Guidewire – K242824 510(k) Summary

I. Submitter

Owner/Operator:	Lake Region Medical
Address:	340 Lake Hazeltine Drive Chaska, MN 55318
Establishment Registration Number:	2126666
Primary Contact Person:	Clara Lee, Sr. Regulatory Affairs Specialist
Email:	clara.lee@intege.net
Phone:	(952) 641 5423
Date Prepared:	September 16, 2024

II. Subject Device

Device Name/Trade Name:	PTFE Guidewire
Common Name:	Catheter Guidewire
Classification Name:	Catheter Guidewire (21 CFR §870.130)
Regulatory Class:	Class II
Product code:	DQX

III. Predicate Device

Device Name:	Cardiovascular and Vascular Guidewire
Manufacturer:	Lake Region Medical
510(k) Number:	K935170
Regulatory Class:	Class II (21 CFR §870.130)
Product Code:	DQX

IV. Device Description

PTFE guidewire is designed to facilitate the placement of devices for diagnostic and interventional procedures. The guidewire is intended for single use.

The guidewire is: .032” diameter and is 200cm in length. The guidewire is composed of three primary components: PTFE coating, a coil and a core. The core and coil are made of 304 stainless steel (ASTM A313). The coil is coated with low-friction polytetrafluoroethylene (PTFE). The coil provides the outer shell while the core is fit inside the inner diameter of the coil. The core provides the stiffness to the guidewire body and flexibility in the J-tip. The core and coil are secured together using a weld on both the distal and proximal of the guidewire.

The guidewire is sterilized using ethylene oxide. The guidewire is loaded into a dispenser hoop and is provided with a J-straightener, which is used to aid the insertion of the guidewire into the delivery device. There are no accessories packaged with the guidewires.

V. Indications for Use

To facilitate the placement of devices for diagnostic and interventional procedures. These guidewires are not intended for PTCA use.

VI. Comparison with the Predicate Device

The PTFE Guidewire is substantially equivalent to the predicate device. The PTFE Guidewire has the same indications for use/intended use including the disease, condition, and patient population, and principles of operation as the legally marketed Cardiovascular and Vascular Guidewire (K935170). Both the predicate device and the subject device are general use guidewires that are intended to facilitate the placement of devices for diagnostic and interventional procedures as specified in Indications for Use. The functional characteristics of the PTFE Guidewire are identical to the predicate device with regards to material, dimensions, and method of constructions.

VII. Summary of Testing Data

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

- **FDA Pre-Conditioning**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Simulated Use**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Tip Flexibility**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Torque Strength**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Particulate Residue**: Tested in accordance with FDA guidance and USP 788. The predetermined acceptance criteria were met.
- **ISO Fracture Resistance**: Tested in accordance with FDA guidance and EN ISO 11070:2014 /A1:2018 Annex F. The predetermined acceptance criteria were met.
- **ISO Flex**: Tested in accordance with FDA guidance and EN ISO 11070:2014/A1 2018. The predetermined acceptance criteria were met.
- Corrosion Resistance: Tested in accordance with FDA guidance and EN ISO 10555-1:2023. The predetermined acceptance criteria were met.
- **Lubricity/Device Compatibility**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Radiopacity**: Tested in accordance with FDA guidance and EN ISO 11070:2014/A1:2018. The predetermined acceptance criteria were met.
- **Body Stiffness**: Tested in accordance per internal requirement. The predetermined acceptance criteria were met.
- **Kink Resistance**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Dimensional - Outer Diameter**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Dimensional – Length**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Dimensional – J Tip Shape**: Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.

- **Coating Integrity**: Tested in accordance with FDA guidance and EN ISO 11070:2014/A1:2018. The predetermined acceptance criteria were met.
- **Distal Tip Pull Test (Tensile Strength):** Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Visual Inspection**: Tested in accordance with FDA guidance, internal requirements, and EN ISO 11070:2014/A1:2018. The predetermined acceptance criteria were met.
- **Pouch Peel Strength**: Tested in accordance with FDA guidance and ASTM F88/F88M-23. The predetermined acceptance criteria were met.
- **Dye Penetration**: Tested in accordance with FDA guidance and ASTM F1929-23. The predetermined acceptance criteria were met.
- **Bubble Leak**: Tested in accordance with FDA guidance, ASTM F2096-11 (Reapproved 2019), and EN ISO 11607-1:2020/A1:2023. The predetermined acceptance criteria were met.
- **Device Shelf Life**: Tested in accordance with FDA guidance and ASTM F1980-21. The predetermined acceptance criteria were met.
- **Packaging Integrity**: Tested in accordance with FDA guidance, ASTM D4169023, and ISTA 3A (2018). 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.

VIII. Conclusion

The PTFE Guidewire, described in this submission, met all design input requirements based on the intended use and supports the conclusion that the PTFE Guidewire does not raise new questions of safety and effectiveness. The results of these tests support a determination of substantial equivalence to the predicate device, the Cardiovascular & Vascular Guidewire (K935170).