March 19, 2026

Lake Region Medical
Amy Carter
Regulatory Affairs Specialist
Parkmore W. Business Park
Galway, H91 CK22
Ireland

Re: K253746
Trade/Device Name: Enroute Transcarotid 0.014" Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: February 16, 2026
Received: February 17, 2026

Dear Amy Carter:

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 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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2026.03.19 15:52:29 -04'00'

for 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253746

Device Name
Enroute 0.014" Transcarotid Guidewire

Indications for Use *(Describe)*
The Enroute Transcarotid 0.014" Guidewire is intended for use in the peripheral vasculature, inclusive of the carotid artery.

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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Enroute Transcarotid 0.014'' Guidewire–510(k) Summary

I. Submitter

Owner/Operator:	Lake Region Medical
Address:	Parkmore West Business Park, Galway, Ireland H91 CK22
Establishment Registration Number:	3006010712
Primary Contact Person:	Amy Carter, Regulatory Affairs Specialist
Alternate Contact Person:	Catherine Magrath, Senior Regulatory Affairs Specialist
Email:	amy.carter@integer.net catherine.magrath@integer.net
Phone:	+353 91 385 037
Date Prepared:	November 25, 2025

II. Subject Device

Device Name/Trade Name:	Enroute 0.014'' Transcarotid Guidewire
Common Name:	Guidewire
Classification Name:	Catheter Guidewire (21 CFR §870.1330)
Regulatory Class:	Class II
Product code:	DQX

III. Predicate Device

Device Name:	Enroute 0.014'' Guidewire
Manufacturer:	Lake Region Medical
510(k) Number:	K160643
Regulatory Class:	Class II (21 CFR §870.1330)
Product Code:	DQX

IV. Device Description

The ENROUTE Transcarotid 0.014" Guidewire is a disposable medical device designed for single use only. It consists of a 95cm PTFE coated 0.014" diameter stainless steel core wire, one end of which is reduced in diameter over approximately 9.5cm in a progressive fashion through a centerless grinding operation. The profile of this reduced section affords the product an area of reduced stiffness. The distal tip section is

flattened to further reduce stiffness and enable the tip to be shaped. The distal section is covered with a 5cm platinum tungsten spring coil. This provides for greater visibility on x-ray equipment (radiopacity). A hydrophilic coating is applied to the distal section to enhance lubricity. The product is available in a straight configuration.

V. Indications for Use

The ENROUTE Transcarotoid 0.014'' Guidewire is intended for use in the peripheral vasculature, inclusive of the carotid artery.

VI. Comparison with the Predicate Device

This Special 510K for the ENROUTE Transcarotid 0.014''Guidewire is being submitted due to a change in Lake Region Medical's present suppliers of PTFE coating who are exiting the market, which impacts the Enroute 0.014'' Guidewire device.

As a result of a supplier forced discontinuation, Lake Region Medical has sourced alternative suppliers of PTFE coating to maintain a continuous supply of material.

The Enroute Transcarotid 0.014'' Guidewire with the proposed PTFE coating is substantially equivalent to the selected predicate coating as the devices are part of Lake Region Medical's Enroute Guidewire family. The Enroute Transcarotid 0.014'' Guidewire with the proposed PTFE coating has the same principles of operation as the legally marketed Enroute 0.014'' Guidewire. The functional characteristics of the Enroute 0.014'' Transcarotid Guidewire with the proposed PTFE coating guidewire are substantially equivalent to the predicate Enroute 0.014'' Guidewire- with regards to material, dimensions and method of construction. The design modifications to the new device -Enroute Transcarotid 0.014'' Guidewire with proposed PTFE coating include differences in the PTFE coating on the device. Performance and safety testing have shown that the device continues to meet its indications for use.

VII. Summary of Testing Data

Non-clinical (bench) performance testing was performed in order to demonstrate that the Enroute Transcarotid 0.014'' 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. Samples were analyzed according to predetermined acceptance criteria utilized by the predicate device (K160643). In addition, FDA guidance *Coronary, Peripheral and Neurovascular Guidewires Performance Tests and Recommended Labeling (October 10, 2019)* was utilized to support demonstrating substantial equivalence.

- **Pre-Conditioning**

  (FDA Guidance: 16007 Section G.1 – Pre-Conditioning). Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.

- **Dimensional Test**

  (FDA Guidance: 16007 Section G.3 – Dimensional Verification). Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.

- **Visual Examination**
  (FDA Guidance: 16007 Section G.4 – Visual Inspection). Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **PTFE Coating Adherence (Saline Soak and Wipe Test)**
  (FDA Guidance: 16007 Section G.10 – Coating Integrity). Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Core Wire Fracture and PTFE Coating Mandrel Adhesion Test**
  (FDA Guidance: 16007 Section G.10 – Coating Integrity). Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **FDA Guidewire Coating Integrity Test**
  (FDA Guidance: 16007 Section G.10 – Coating Integrity). Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Catheter Compatibility**
  (FDA Guidance: 16007 Section G.5 – Simulated Use). Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Guidewire Particulate Residue Test**
  (FDA Guidance: 16007 Section G.11 – Particulate Evaluation). Tested in accordance with FDA guidance. The predetermined acceptance criteria were met.
- **Oak River Pinch Test**
  (FDA Guidance: 16007 Section G.12 – Lubricity). Tested in accordance with FDA guidance. 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 Enroute Transcarotid 0.014'' Guidewire with the proposed PTFE coating described in this submission, met all design input requirements based on the indications for use. The results of these tests support a determination of substantial equivalence to the predicate device.