August 27, 2026

Piraeus Medical, Inc.
Sarah Kabanuk
COO
7351 Kirkwood Lane N, Suite 116
Maple Grove, Minnesota 55369

Re: K260751
Trade/Device Name: 35 Helix Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: July 23, 2026
Received: July 24, 2026

Dear Sarah Kabanuk:

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,

NAIRA MURADYAN -S

Naira Muradyan, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260751

Please provide the device trade name(s).

35 Helix Guidewire

Please provide your Indications for Use below.

The 35 Helix Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary, K260751

A. Submitter Information

Submitter's Name:	Piraeus Medical, Inc.
Address:	7351 Kirkwood Lane N, Suite 116 Maple Grove, MN 55369, USA
Contact Person:	Sarah Kabanuk
Telephone:	507-782-0184
Email:	skabanuk@piraeusmedical.com
Date of Preparation:	March 6th, 2026

B. Correspondent Information

Contact Name:	Sarah Kabanuk
Telephone:	507-782-0184

C. Subject Device

Proprietary Name:	35 Helix™ Guidewire
Common/Usual Name:	Guidewire
Classification Name:	Guide, Wire, Catheter, Neurovasculature
Product Codes:	MOF, DQX
Regulation:	21 CFR 870.1330

D. Predicate Device

Proprietary Name:	Aristotle® Colossus® Guidewire
Common/Usual Name:	Guidewire
Classification Name:	Guide, Wire, Catheter, Neurovasculature
Product Codes:	MOF, DQX
Regulation:	21 CFR 870.1330
Manufacturer:	Scientia Vascular, Inc.
510(k) #:	K222437

E. Device Description

The 35 Helix Guidewire is a 0.035" diameter guidewire designed to facilitate access to neuro and peripheral vasculatures. It is supplied sterile for single use only and is available in a standard stiffness profile with a length of 180 cm. The guidewire is offered pre-shaped with either a straight tip or a round curve distal tip. The guidewire is constructed of nitinol and features a distal radiopaque polymer jacket to facilitate fluoroscopic visualization. A hydrophilic coating on the distal segment is to reduce friction during manipulation in vessels. The guidewire is provided with an introducer, to aid with guidewire insertion into a catheter hub and/or rotating hemostasis valve (RHV), and a torque device to attach to the proximal portion of the guidewire to facilitate steering.

F. Intended Use

The 35 Helix Guidewire is intended for use by a physician to help introduce and position catheters or other interventional devices within the neuro and peripheral vasculature.

G. Indications for Use

The 35 Helix Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.

H. Comparison of Technological Characteristics

Shown in the table below is the comparison of technological characteristics for the 35 Helix Guidewire to those of the predicate device, Aristotle Colossus Guidewire (K222437).

Table 1: Comparison of Predicate and Subject Devices

Device Attribute	Predicate Device (K222437)	Subject Device (K260751)
Regulation / Product Code	Class II, MOF, DQX, 21 CFR 870.1330	Same
Indications for Use	The Aristotle Colossus Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.	The 35 Helix Guidewire is intended for general vascular use within the neuro and peripheral vasculatures to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.
Intended Use	The Aristotle Colossus Guidewire is intended for use by a physician to help introduce and position catheters or other interventional devices within the neuro and peripheral vasculature.	The 35 Helix Guidewire is intended for use by a physician to help introduce and position catheters or other interventional devices within the neuro and peripheral vasculature.
Wire Diameter Maximum	0.035" (0.88 mm)	Same
Wire Diameter Profile	0.018"- 0.035"	0.024" - 0.035"
Device Length	150 cm to 300 cm	180 cm
Flex (Tip) Length	35 cm	25 cm
Tip Type and Shape	Straight, Shapeable	Pre-Shaped Straight Pre-Shaped Round Curve
Flexibility (stiffness)	Standard	Same
Wire Material	Core Wire: Stainless Steel	Core Wire: Nitinol
Coatings	Distal End: Hydrophilic	Same
	Distal Coated Length: 46 cm	Distal Coated Length: 80 cm
	Proximal End: Polytetrafluoroethylene (PTFE)	Proximal End: None
Distal Portion Radiopacity	Tip includes a radiopaque platinum wire marker coil that is 10 cm long	Tip includes a radiopaque loaded polymer section that is 13.75 cm long
Accessories	Guidewire Introducer, Torque Device, Shaping Mandrel	Guidewire Introducer, Torque Device
Packaging Configuration	High-Density Polyethylene (HDPE) Tube, Tyvek Pouch, Carton, Shipper Box	Same
Sterilization Method	100% Ethylene Oxide (EO)	Same
Shelf Life	1 year	6 months

I. Performance Data Supporting Substantial Equivalence

A summary of the supportive testing is presented in Table 2. These tests were performed per company approved protocols, test methods, and performance standards.

Table 2: Test and Performance Specifications

Test	Test Method Summary [standard and/or guidance]	Result
Dimensional Verification	The guidewire diameter, usable length and coating length were measured [ISO 11070, FDA guidance "Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling" (FDA-2018-D-1775)].	Pass
Visual Inspection	The guidewire was examined for surface defects and extraneous matter which could cause trauma to vessels during use. The distal tip was inspected to confirm the presence of smooth, rounded edges and correct tip configuration [ISO 11070, FDA-2018-D-1775].	Pass
Radiopacity	Radiopacity testing per ASTM F640.	Pass
Delivery, Compatibility, and Retraction (Trackability and Simulated Use)	The guidewire can be inserted, tracked and removed per the instructions for use (IFU) within a simulated use model without damage to the guidewire [FDA-2018-D-1775].	Pass
Pushability	The proximal shaft of the guidewire has sufficient stiffness that the user can push the guidewire to the target anatomy without buckling [FDA-2018-D-1775].	Pass
Tip Flexibility	Measure force to deflect guidewire tips at 5 mm, 10 mm, and 20 mm test lengths [FDA-2018-D-1775].	Pass
Torqueability/Torque Strength	Torque response (average input-to-output lag) and torque turns to failure were measured in an anatomical model [FDA-2018-D-1775].	Pass
Particulate	Particulates of various size ranges counted after simulated use in a tortuous path [FDA-2018-D-1775].	Pass
Coating Lubricity and Durability	Frictional force of coated guidewires was determined after simulated use in a tortuous path [FDA-2018-D-1775].	Pass
Tip Pull and Tensile Strength	Tensile strength / Tip Pull / Peak tensile force of the entire length of the guidewire [ISO 11070, FDA-2018-D-1775].	Pass
Kink Resistance	There shall be no kinking of shaft (permanent deformation) after simulated use [FDA-2018-D-1775].	Pass
Corrosion Resistance	Corrosion resistance evaluated the metallic components related to corrosion contacting the intended fluid path [ISO 11070].	Pass
Fracture and Flexing	The guidewire does not fracture, loosen, or fail during repeated, tortuous use [ISO 11070].	Pass
Compatibility with Other Devices	The guidewire is compatible with catheters and interventional devices up to the minimum size indicated in the device labeling [FDA-2018-D-1775].	Pass
Usability and Design Validation	Physicians evaluated subject and predicate guidewires for various performance characteristics in an anatomically relevant model [IEC 62366-1, FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" (FDA-2011-D-0469)].	Pass
Accessory Compatibility	The guidewires shall be compatible with their packaged accessories (introducer and torque device).	Pass

Coating Integrity	Coating coverage was assessed after simulated use in a tortuous path anatomical model [ISO 11070, FDA-2018-D-1775].	Pass

J. Biocompatibility Testing

The following biocompatibility testing was conducted for the 35 Helix Guidewire:

Table 3: Summary of Subject Device Biocompatibility Testing Performed

Test	Test Method Summary	Conclusion of Testing
Cytotoxicity (MEM Elution)	Test in accordance with ISO 10993-5	Non-cytotoxic
Sensitization	Test in accordance with ISO 10993-10	Non-sensitizing
Irritation	Tested in accordance with ISO 10993-23	Non-irritating
Acute Systemic Toxicity	Tested in accordance with ISO 10993-11	Non-toxic
Material Mediated Rabbit Pyrogen	Tested in accordance with ISO 10993-11 and USP <151>	Non-pyrogenic
Direct Contact and Extract Method Hemolysis	Tested in accordance with ISO 10993-4 and ASTM F756	Non-hemolytic
Platelet and Leukocyte Count Assay	Tested in accordance with ISO 10993-4	The subject device had similar or lesser impact on platelet and leukocyte counts when compared to the predicate.
Sc5b-9 Complement Activation	Tested in accordance with ISO 10993-4	The subject device had similar potential to activate the complement system when compared to the predicate.
In vitro blood flow loop	Tested in accordance with ISO 10993-4	The thrombus deposition on the subject device was similar to or less than that of the comparator device.
Partial Thromboplastin Time (PTT) Test	Tested in accordance with ISO 10993-4	No effect on the PTT. The subject device and the predicate are considered similar.

K. Sterilization

The 35 Helix Guidewire is sterilized using a validated EO process with a sterility assurance level of $1x10^{-6}$ validated per the overkill method in accordance with ISO 11135, "Sterilization of Health-Care Products - Ethylene Oxide - Requirements for The Development, Validation and Routine Control of A Sterilization Process For Medical Devices", and tested for EO and ethylene chlorohydrin (ECH) residuals and bacterial endotoxin levels.

L. Shelf Life and Packaging

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance to support a 6-month shelf-life claim. Device and package performance was verified by functional and performance testing.

M. Conclusions

The subject device, 35 Helix Guidewire, has the same intended use, same indications for use, same fundamental design and similar device features as the predicate device. The differences in technological characteristics have been evaluated through testing and risk evaluation, and do not raise new or different questions of safety and effectiveness, supporting that the subject device is substantially equivalent to the predicate.