April 29, 2026

Scientia Vascular, Inc.
Max Alfonso
Regulatory Affairs Manager
2460 South 3270 West
West Valley City, Utah 84119

Re: K253579
Trade/Device Name: Aristotle 14 Guidewire; Aristotle 18 Guidewire; Aristotle 24 Guidewire; Zoom Wire 14 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: March 27, 2026
Received: March 27, 2026

Dear Max Alfonso:

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, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
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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.

510(k) Number *(if known)*
K253579

Device Name
Aristotle 14 Guidewire; Aristotle 18 Guidewire; Aristotle 24 Guidewire; Zoom Wire 14 Guidewire

Indications for Use *(Describe)*

Aristotle 14 Guidewire
The Aristotle 14 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.

Aristotle 18 Guidewire
The Aristotle 18 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.

Aristotle 24 Guidewire
The Aristotle 24 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.

Zoom Wire 14 Guidewire
The Zoom Wire 14 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.

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

510(k) Sponsor: Scientia Vascular, Inc.
2460 South 3270 West
West Valley City, UT 84119
Tel (888) 385-9016

Contact Person(s): Max Alfonso
Regulatory Affairs Manager
Tel: (888) 385-9016
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Date Prepared: April 22, 2026

Table 1. Subject Device Information

Aristotle 14 Guidewire	
Trade Name:	Aristotle 14 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Subsequent Product Code	DQX
Predicate Device:	Aristotle 14 Guidewire (K173235)
Aristotle 18 Guidewire	
Trade Name:	Aristotle 18 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Subsequent Product Code	DQX
Predicate Device:	Aristotle 18 Guidewire (K231954)
Aristotle 24 Guidewire	
Trade Name:	Aristotle 24 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Subsequent Product Code	DQX
Predicate Device:	Aristotle 24 Guidewire (K231954)
Zoom Wire 14 Guidewire	
Trade Name:	Zoom Wire 14 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Primary Product Code:	MOF
Subsequent Product Code	DQX
Predicate Device:	Zoom 14 Guidewire (K201760)

DEVICE DESCRIPTION

The Scientia Vascular's Aristotle 14, Aristotle 18, Aristotle 24, and Zoom Wire 14 Guidewires ("the guidewires") are steerable guidewires with a shapeable tip to aid in accessing the neuro and peripheral vasculatures. The guidewires are supplied sterile, for single use only, in the following diameters, stiffness profiles, and lengths:

Aristotle 14 Guidewire	
Diameter	0.014"
Stiffness Profiles	Soft, Standard
Lengths	200 cm, 300 cm

Aristotle 18 Guidewire	
Diameter	0.018"
Stiffness Profiles	Soft, Standard, Support
Length	200 cm, 300cm

Aristotle 24 Guidewire	
Diameter	0.024"
Stiffness Profiles	Soft, Standard, Support
Length	200 cm, 300cm

Zoom Wire 14 Guidewire	
Diameter	0.014"
Stiffness Profiles	Support, Extra Support
Lengths	200 cm, 300 cm

The distal portion of each guidewire's tip includes a radiopaque platinum wire marker coil to facilitate fluoroscopic visualization. All guidewires have a hydrophilic polymer coating on the distal portion and a polytetrafluoroethylene (PTFE) coating on the proximal portion to reduce friction during manipulation in vessels.

The guidewires are provided with an accessory kit consisting of an introducer (to aid with the insertion of the guidewire into a catheter hub and/or a hemostasis valve), a torque device (to attach to the proximal portion of the guidewire to facilitate gripping and manipulation of the guidewire during use), and a shaping mandrel (to aid in shaping the flexible tip of the guidewire). These accessory devices are included to facilitate use of the guidewires and are not intended to contact the patient's body.

INDICATIONS FOR USE

Aristotle 14 Guidewire
The Aristotle 14 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.

Aristotle 18 Guidewire
The Aristotle 18 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.

Aristotle 24 Guidewire
The Aristotle 24 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.

Zoom Wire 14 Guidewire
The Zoom Wire 14 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 subject guidewires are intended for use by a physician to help introduce and position catheters or other interventional devices within the neuro and peripheral vasculature.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject devices have the following similarities to the previously cleared predicate devices:

- The same indications for use,
- The same intended use,
- The same operating principle,
- The same basic guidewire design,
- Similar materials, and
- The same packaging materials and sterilization processes.

The tables (**Table 2 - 5**) below provide additional details on the technological characteristics of the subject devices compared to their respective predicate devices.

Table 2. Aristotle 14 Guidewire Technological Characteristics Comparison

Characteristic	Subject Device Aristotle 14 Guidewire (K253579)	Predicate Aristotle 14 Guidewire (K173235)	Comparison
Anatomical Location	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
Dimensions	***O.D.:*** 0.014" (0.36 mm) ***Length*:** 200 cm, 300 cm	***O.D.:*** 0.014" (0.36 mm) ***Length*:** 200 cm, 300 cm	Same
Core Wire	Stainless Steel	Stainless Steel	Same
Distal Tip	Shapeable ***Length:*** 35 cm ***Material:*** Nitinol	Shapeable ***Length:*** 35 cm ***Material:*** Nitinol	Same
Stiffness Profiles	Soft, standard	Soft, standard	Same
Coatings	***Distal End:*** Hydrophilic (proposed)	***Distal End:*** Hydrophilic	Different
	Proximal End: PTFE	***Proximal End:*** PTFE	Same

Characteristic	Subject Device Aristotle 14 Guidewire (K253579)	Predicate Aristotle 14 Guidewire (K173235)	Comparison
Radiopaque Marker	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	Same
Centering Coil	1 centering coil	1 centering coil	Same
Shaping Mandrel (Accessory)	Provided with each guidewire	NA	Cleared in K220398
Guidewire Introducer (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Torque Device (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Sterilization Method	100% Ethylene Oxide (EO)	100% EO	Same
Shelf Life	1 year	3 year	Different

Table 3. Aristotle 18 Guidewire Technological Characteristics Comparison

Characteristic	Subject Device Aristotle 18 Guidewire (K253579)	Predicate Aristotle 18 Guidewire (K231954)	Comparison
Anatomical Location	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
Dimensions	***O.D.:*** 0.018" (0.46 mm) ***Length:*** 200 cm, 300 cm	***O.D.:*** 0.018" (0.46 mm) ***Length:*** 200 cm, 300 cm	Same
Core Wire	Stainless Steel	Stainless Steel	Same
Distal Tip	Shapeable ***Length:*** 35 cm ***Material:*** Nitinol	Shapeable ***Length:*** 35 cm ***Material:*** Nitinol	Same
Stiffness Profiles	Support, standard, soft	Support, standard, soft	Same
Coatings	***Distal End:*** Hydrophilic (proposed)	***Distal End:*** Hydrophilic	Different
	Proximal End: PTFE	***Proximal End:*** PTFE	Same

Characteristic	Subject Device Aristotle 18 Guidewire (K253579)	Predicate Aristotle 18 Guidewire (K231954)	Comparison
Radiopaque Marker	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	Same
Centering Coil	1 centering coil	1 centering coil	Same
Shaping Mandrel (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Guidewire Introducer (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Torque Device (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Sterilization Method	100% EO	100% EO	Same
Shelf Life	1 year	3 year	Different

Table 4. Aristotle 24 Guidewire Technological Characteristics Comparison

Characteristic	Subject Device Aristotle 24 Guidewire (K253579)	Predicate Aristotle 24 Guidewire (K231954)	Comparison
Anatomical Location	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
Dimensions	***O.D.:*** 0.024" (0.61 mm) ***Length:*** 200 cm, 300 cm	***O.D.:*** 0.024" (0.61 mm) ***Length:*** 200 cm, 300 cm	Same
Core Wire	Stainless Steel	Stainless Steel	Same
Distal Tip	Shapeable ***Length:*** 35 cm ***Material:*** Nitinol	Shapeable ***Length:*** 35 cm ***Material:*** Nitinol	Same
Stiffness Profiles	Support, standard, soft	Support, standard, soft	Same
Coatings	***Distal End:*** Hydrophilic (proposed)	***Distal End:*** Hydrophilic	Different
	Proximal End: PTFE	***Proximal End:*** PTFE	Same

Characteristic	Subject Device Aristotle 24 Guidewire (K253579)	Predicate Aristotle 24 Guidewire (K231954)	Comparison
Radiopaque Marker	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	Same
Centering Coil	2 centering coils	2 centering coils	Same
Bushing	1 bushing	1 bushing	Same
Shaping Mandrel (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Guidewire Introducer (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Torque Device (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Sterilization Method	100% EO	100% EO	Same
Shelf Life	1 year	3 year	Different

Table 5. Zoom Wire 14 Guidewire Technological Characteristics Comparison

Characteristic	Subject Device Zoom Wire 14 Guidewire (K253579)	Predicate Zoom 14 Guidewire (K201760)	Comparison
Anatomical Location	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
Dimensions	***Max O.D.:*** 0.014" (0.36 mm) ***Length:*** 200 cm, 300 cm	***Max O.D.:*** 0.014" (0.36 mm) ***Length:*** 200 cm, 300 cm	Same
Core Wire	Stainless Steel	Stainless Steel	Same
Distal Tip	Shapeable ***Length:*** 35 cm ***Material:*** Nitinol	Shapeable ***Length:*** 35 cm ***Material:*** Nitinol	Same
Stiffness Profiles	Support, extra support	Support, extra support	Same
Coatings	***Distal End:*** Hydrophilic (proposed)	***Distal End:*** Hydrophilic	Different

Characteristic	Subject Device Zoom Wire 14 Guidewire (K253579)	Predicate Zoom 14 Guidewire (K201760)	Comparison
	Proximal End: PTFE	***Proximal End:*** *PTFE*	Same
Radiopaque Marker	Radiopaque marker at distal tip	Radiopaque marker at distal tip	Same
Centering Coil	1 centering coil	1 centering coil	Same
Bushing	None	None	Same
Shaping Mandrel (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Guidewire Introducer (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Torque Device (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Sterilization Method	100% EO	100% EO	Same
Shelf Life	1 year	3 year	Different

The subject devices have a different hydrophilic coating on the distal end of the guidewire. This difference does not raise new questions of safety and effectiveness, nor does it result in new risks for the subject devices. Testing and evaluation (see below) of the subject devices have been performed with regards to this characteristic and demonstrated the subject devices perform as intended.

NON-CLINICAL PERFORMANCE TESTS

Biocompatibility

A biological risk assessment was performed in accordance with recommendations in the ISO 10993 series and ISO 14971:2019 to assess the impact of the different hydrophilic coating on the biocompatibility profile of the subject devices. The subject devices are considered externally communicating devices with circulating blood contact for a limited duration (≤ 24 hours) and the following tests were performed to assess the modification made to the direct blood contacting region of the guidewires:

Table 6. Summary of Biocompatibility Testing

Test	Test Method Summary	Conclusion
Cytotoxicity	MEM elution cell culture observed for cytotoxic reactivity.	Pass: Non-cytotoxic.

Material-mediated Pyrogenicity	Study animals were observed for individual temperature rise.	Pass: Non-pyrogenic.
Sensitization	Study animals with subject device were observed for dermal sensitization.	Pass: Non-sensitizing.
Irritation	Study animals with subject device were observed for dermal reaction.	Pass: Non-irritant.
Acute Systemic Toxicity	Study animals with the subject device were observed for abnormal clinical signs indicative of toxicity.	Pass: No evidence of acute systemic toxicity.
Direct and Indirect Hemolysis	The difference between the hemolytic indexes of the subject device and the negative control was evaluated.	Pass: Non-hemolytic. (Direct and Indirect)
Complement Activation of SC5b-9	Comparison of the subject device SC5b-9 value to the predicate device for all exposure times was performed.	Pass: The test article complement activation was similar to the comparator device.
In Vitro Thrombogenicity	Device is placed in an in vitro blood loop for three runs. The thrombus score for the subject and predicate device is observed.	Pass: Thromboresistant.

Sterilization

The existing validated sterilization cycle uses 100% EO to achieve a sterilization assurance level (SAL) of 10^{-6}.

Bench Performance Testing

Following review of the risk assessments conducted in accordance with ISO 14971:2019 performance testing was performed on the subject devices. Additional performance tests to evaluate continued compliance with ISO 11070:2014, "*Sterile single-use intravascular introducers, dilators and guidewires,*" and the FDA guidance document, "*Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" (2019), were also performed. Table 7 summarizes these tests and their results below.

Table 7. Summary of Bench Performance Tests

Test	Test Method Summary	Results
Visual Inspection and Dimensional Verification	Test per ISO 11070	Acceptance criteria met
Coating Lubricity, Durability, and Integrity Assessment	Test per ISO 11070 and FDA guidance document "*Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met
Torqueability	Test per FDA guidance document "*Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met

Flexing	Test per ISO 11070	Acceptance criteria met
Simulated Use	Guidewires were tested for use with a microcatheter, the guidewire introducer, and torque device while navigating to target locations in a simulated use model. Test per FDA guidance document "*Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met
Particulate	Particulate measured and counted after guidewire use in a simulated pathway model with a microcatheter and the guidewire introducer. Test per FDA guidance document "*Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met
Corrosion Resistance	Test per FDA guidance document "*Coronary, Peripheral and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met

Animal Testing

No animal testing was deemed necessary to support the substantial equivalence of the subject devices.

Clinical Testing

No clinical testing was deemed necessary to support the substantial equivalence of the subject devices.

CONCLUSION

The Aristotle 14 Guidewire, Aristotle 18 Guidewire, Aristotle 24 Guidewire, and Zoom Wire 14 Guidewire have the same intended use and indications for use statement as their respective predicate device. The identified technological difference does not raise new questions of safety or effectiveness regarding the use of the subject devices. Risk evaluation along with bench and biocompatibility testing, was completed for the subject devices. The testing and risk evaluation demonstrate that the subject devices are substantially equivalent to their respective predicate device.