August 6, 2026

Scientia Vascular, Inc.
Jamila Abou-Bakr
Regulatory Affairs Specialist
2460 South 3270 West
West Valley City, Utah 84119

Re: K260223
Trade/Device Name: Aristotle Mini Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: July 3, 2026
Received: July 6, 2026

Dear Jamila Abou-Bakr:

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
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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.	K260223

Please provide the device trade name(s).

Aristotle Mini Guidewire

Please provide your Indications for Use below.

The Aristotle Mini 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 (K260223, Per 21 CFR 807.92)

510(k) Sponsor: Scientia Vascular, Inc.

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Date Prepared: July 14, 2026

Table 1. Subject Device Information

Trade Name:	Aristotle Mini 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 (K243938)
Reference Device:	PVS 1600 Synchro 0.010" Guidewire (K032146)

DEVICE DESCRIPTION

Scientia Vascular's Aristotle Mini Guidewire has a 0.011" distal/0.012" proximal outer diameter (OD) and is compatible with catheters with a minimum inner diameter of 0.013". The guidewire has a straight, shapeable tip and is supplied in lengths of 200 cm, 225 cm, and 300 cm. It is provided in one stiffness profile – standard.

The Aristotle Mini Guidewire is intended to facilitate access to distal neuro and peripheral vasculature, and it can be used with guide catheters or intermediate catheters. The guidewire incorporates a radiopaque platinum coil to facilitate fluoroscopic visualization, and is designed with variable shaft stiffness from the flexible distal tip to the more rigid proximal end. The distal outer surface of the guidewire is coated with a hydrophilic coating, and the proximal outer surface is coated in polytetrafluoroethylene (PTFE). The coated surfaces are intended to reduce friction during manipulation of the guidewire within the vessel and/or catheter.

A shaping mandrel, guidewire introducer, and torque device accessories are included with the Aristotle Mini Guidewire.

INDICATIONS FOR USE

The Aristotle Mini 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 Mini Guidewire is 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 device is substantially equivalent to the predicate device and has the same or similar:

- Indications for use
- Materials

- Technological characteristics
- Packaging and sterilization of devices

Table 2 provides details on the technological characteristics of the subject device compared to the predicate device and the reference device.

Table 2. Technological Characteristics Comparison

Characteristic	Subject Device Aristotle Mini Guidewire (K260223)	Predicate Device Aristotle 14 Guidewire (K243938)	Reference Device PVS 1600 Synchro 0.010" Guidewire (K032146)*
Indications for Use	The Aristotle Mini 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 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.	The PVS 1600 Synchro 0.010" Guidewire series of products are intended for general intravascular use, including the neuro and peripheral vasculature. The device can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. The device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.
Anatomical Location	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Neuro and peripheral vasculature
Dimensions	***OD:*** 0.011" distal / 0.012" proximal	***OD:*** 0.014"	***OD:*** 0.010" distal / 0.012" proximal
	Length: 200 cm, 225 cm, 300 cm	***Length:*** 200 cm, 300 cm	***Length:*** 180 – 300 cm
Core Wire	304v Stainless Steel	304v Stainless Steel	304 Stainless Steel
Distal Tip	***Length:*** 35 cm ***Material:*** Nitinol	***Length:*** 35 cm ***Material:*** Nitinol	***Length:*** 25-65 cm ***Material:*** Nitinol
Tip Shape	Straight, Shapeable	Straight, Shapeable	Straight, Shapeable

Characteristic	Subject Device Aristotle Mini Guidewire (K260223)	Predicate Device Aristotle 14 Guidewire (K243938)	Reference Device PVS 1600 Synchro 0.010" Guidewire (K032146)*
Stiffness Profiles	Standard	Soft, Standard	Support (Stiff) to Flex (Soft)
Distal Coating	Hydrophilic	Hydrophilic	Hydrophilic
Proximal Coating	PTFE	PTFE	PTFE
Radiopaque Marker	1 radiopaque marker at distal tip ***Length:*** 5 cm	1 radiopaque marker at distal tip ***Length:*** 10 cm	1 radiopaque marker at distal tip ***Length:*** 10 cm
Centering Coil(s)	None	Stainless-steel	NA
Introducer (Accessory)	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire (combined with shaping mandrel)
Torque Device (Accessory)	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire
Shaping Mandrel (Accessory)	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire (combined with introducer)
Packaging Configuration	Single HDPE tubing hoop sealed in Tyvek Pouch	Single HDPE tubing hoop sealed in Tyvek Pouch	Single tubing hoop sealed in pouch
Sterilization Method	100% Ethylene Oxide (EO)	100% Ethylene Oxide (EO)	Irradiation
Shelf Life	1 year	1 year	NA

*Completed based on 510(k) Summary, product labeling, or public information available on the device. Characteristics for which information could not be found have been labeled as not available (NA).

When compared with the predicate device, the subject device has the technological characteristic differences shown in the table above. These differences do not raise new questions of safety and effectiveness for the subject device. To evaluate the effects of these differences, performance testing was conducted to demonstrate the subject device performs as intended.

NON-CLINICAL PERFORMANCE TESTS

Biocompatibility

Biocompatibility testing was performed according to requirements set by FDA guidance document, "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*," and ISO 10993-1, "*Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process.*" The subject device is considered an externally communicating device with circulating blood contact for a limited duration (≤ 24 hours). All manufacturing processes used for the subject device are the same as for the predicate, as well as all materials with the exception of the hydrophilic coating (same coating components, new formulation). Therefore, the following tests were performed with representative devices focusing on biocompatibility of the hydrophilic coating:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity and Pyrogenicity
- Hemocompatibility

Sterilization

The subject device was adopted into an existing validated sterilization cycle that uses 100% EO to achieve a sterilization assurance level (SAL) of 10^{-6}, and testing for EO and ethylene chlorohydrin (ECH) residuals and bacterial endotoxin levels was performed. The subject device followed the requirements of AAMI TIR 28:2016, "*Product adoption and process equivalence for ethylene oxide sterilization*," to ensure it continues to meet the requirements of the following standards:

- ISO 11135:2014/A1:2018, "*Sterilization of Health Care Products - Ethylene Oxide – Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices*"
- ANSI/AAMI/ISO 10993-7:2008, "*Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*"

Bench Performance Testing

Following review of the risk assessments conducted in accordance with ISO 14971:2019 performance testing was performed on the subject device. Performance testing was conducted to ensure compliance with ISO 11070:2014, "*Sterile single-use intravascular introducers, dilators and guidewires*," and per recommendations of the FDA guidance document, "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" (2019).
Table 3 below summarizes these tests and their results:

Table 3. Summary of Bench Performance Tests

Test	Test Method Summary	Results
Visual Inspection and Dimensional Verification	Test per ISO 11070	Acceptance criteria met
Particulate	Particulate measured and counted after use in a simulated pathway model.	Acceptance criteria met
Tensile Testing	Test per ISO 11070	Acceptance criteria met
Kink Resistance	Test per 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
Torque Strength	Test per FDA guidance document, "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met
Tip Flexibility – Column Buckling	Test per FDA guidance document, "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met
Flex and Fracture	Test per ISO 11070	Acceptance criteria met
Shapeability and Tip Shape Retention	Evaluated the distal tip shapeability and shape retention after simulated use.	Acceptance criteria met
Coating Lubricity, Durability, and Integrity	Test per ISO 11070 and FDA guidance document, "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met
Corrosion Resistance	Test per ISO 11070 and FDA guidance document, "*Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling*" *(2019)*	Acceptance criteria met
Compatibility with Agents	Guidewires were tested for compatibility with IsoVue 300, IsoVue 370, DMSO, and heparinized saline.	Acceptance criteria met
Simulated Use and Compatibility	Conducted simulated use in anatomical model designed to simulate the tortuous anatomy of the neurovasculature.	Acceptance criteria met
Usability and Radiopacity Validation	Physicians evaluated subject and comparator guidewires for various performance characteristics in a human cadaver.	Acceptance criteria met

ANIMAL TESTING

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

CLINICAL TESTING

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

CONCLUSION

The subject device has the same intended use and indications for use statement as the predicate device. The identified technological differences do not raise new questions of safety or effectiveness regarding the use of the subject device. The testing demonstrates that the subject device is substantially equivalent to the predicate device.