August 1, 2023

Scientia Vascular, Inc.
Bailey Johannsen
Regulatory Affairs Specialist
3487 West 2100 South, Suite 100
West Valley City, Utah 84119

Re: K231954
Trade/Device Name: Aristotle 18 Guidewire; Aristotle 24 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: June 30, 2023
Received: July 3, 2023

Dear Bailey Johannsen:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231954

Device Name
Aristotle 18 Guidewire; Aristotle 24 Guidewire

Indications for Use *(Describe)*
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.

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.

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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K231954 510(k) SUMMARY

510(k) Sponsor: Scientia Vascular, Inc.

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Date Prepared: July 28, 2023

Table 1. Subject Device Information

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 (K183608)
Reference Device:	Aristotle Colossus Guidewire (K222437)
Reference Device:	Aristotle 14 Guidewire (K173235)
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
Secondary Product Code	DQX
Predicate Device:	Aristotle 24 Guidewire (K192783)
Reference Device:	Aristotle Colossus Guidewire (K222437)
Reference Device:	Aristotle 14 Guidewire (K173235)

DEVICE DESCRIPTION

The Scientia Vascular's Aristotle 18 Guidewire and Aristotle 24 Guidewire 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 18 Guidewire	
Diameter	0.018"
Stiffness Profiles	Soft, Standard, Support
Length	200 cm, 300 cm

Aristotle 24 Guidewire	
Diameter	0.024"
Stiffness Profiles	Soft, Standard, Support
Length	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 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.

The indications for use of the subject Aristotle 18 Guidewire and Aristotle 24 Guidewire are the same as in prior, predicate submissions for the Aristotle 18 Guidewire (K183608) and Aristotle 24 Guidewire (K192783), respectively.

INTENDED USE

The Aristotle 18 Guidewire and Aristotle 24 Guidewire 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,
- The same materials, and
- The same packaging materials and sterilization processes.

The tables (Table 2 and Table 3) below provide additional details on the technological characteristics of the subject devices compared to their respective predicate and reference devices.

Table 2. Aristotle 18 Guidewire Technological Characteristics Comparison (Differences are Bolded)

Characteristic	Subject Device Aristotle 18 Guidewire	Predicate Aristotle 18 Guidewire (K183608)	Reference Device Aristotle Colossus Guidewire (K222437)	Reference Device Aristotle 14 Guidewire (K173235)
Anatomical Location	Same	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Neuro and peripheral vasculature
Dimensions	O.D.: 0.018" (0.46mm) **Length:** 200cm, 300cm	O.D.: 0.018" (0.46mm) **Length:** 200cm	O.D.: 0.035" (0.88mm) **Length:** 150cm – 300cm	O.D.: 0.014" (0.36mm) **Length:** 200cm, 300cm
Core Wire	Same	Stainless Steel	Stainless Steel	Stainless Steel
Distal Tip	Same	Shapeable *Length*: 35cm *Material*: Nitinol	Shapeable *Length:* 35cm *Material:* Nitinol	Shapeable *Length*: 35cm *Material*: Nitinol
Stiffness Profiles	Support, standard, soft	Support, standard, soft	Standard	Soft, standard
Coatings	Same	*Distal End:* Hydrophilic *Proximal End:* PTFE	*Distal End:* Hydrophilic *Proximal End:* PTFE	*Distal End:* Hydrophilic *Proximal End:* PTFE
Radiopaque Marker	Same	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip
Centering Coil	Same	Stainless steel	Stainless steel	Stainless steel
Centering Washer	Does not contain a washer	Does not contain a washer	Stainless steel	Does not contain a washer
Bushing	Does not contain bushing	Does not contain bushing	Nitinol Bushing	Does not contain bushing
Shaping Mandrel (Accessory)	Same	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire
Guidewire Introducer (Accessory)	Same	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire
Torque Device (Accessory)	Same	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire
Sterilization Method	Same	100% Ethylene Oxide (EO)	100% EO	100% EO
Shelf Life	36 Months	36 Months	12 Months	12 Months

Table 3. Aristotle 24 Guidewire Technological Characteristics Comparison (Differences are Bolded)

Characteristic	Subject Device Aristotle 24 Guidewire	Predicate Aristotle 24 Guidewire (K192783)	Reference Device Aristotle Colossus Guidewire (K222437)	Reference Device Aristotle 14 Guidewire (K173235)
Anatomical Location	Same	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Neuro and peripheral vasculature
Dimensions	O.D.: 0.024" (0.61mm) **Length:** 200cm, 300cm	O.D.: 0.024" (0.61mm) **Length:** 200cm	**O.D.:** 0.035" (0.88mm) **Length:** 150cm – 300cm	***O.D.:*** 0.014" (0.36mm) ***Length*:** 200cm, 300cm
Core Wire	Same	Stainless Steel	Stainless Steel	Stainless Steel
Distal Tip	Same	Shapeable *Length:* 35cm *Material:* Nitinol	Shapeable *Length:* 35cm *Material:* Nitinol	Shapeable *Length*: 35cm *Material*: Nitinol
Stiffness Profiles	Support, standard, soft	Support, standard, soft	Standard	Soft, standard
Coatings	Same	*Distal End:* Hydrophilic *Proximal End:* PTFE	*Distal End:* Hydrophilic *Proximal End:* PTFE	*Distal End:* Hydrophilic *Proximal End:* PTFE
Radiopaque Marker	Same	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip
Centering Coil	Same	Stainless steel	Stainless steel	Stainless steel
Centering Washer	Does not contain a washer	Does not contain a washer	Stainless steel	Does not contain a washer
Bushing	Nitinol bushing	Nitinol bushing	Nitinol bushing	Does not contain bushing
Shaping Mandrel (Accessory)	Same	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire
Guidewire Introducer (Accessory)	Same	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire
Torque Device (Accessory)	Same	Provided with each guidewire	Provided with each guidewire	Provided with each guidewire
Sterilization Method	Same	100% EO	100% EO	100% EO
Shelf Life	36 Months	36 Months	12 Months	12 Months

The Aristotle 18 Guidewire and Aristotle 24 Guidewire have been modified to include additional models of longer length with added 100 cm of proximally PTFE coated guidewire for a total guidewire length of 300 cm. The Aristotle 18 and Aristotle 24 Guidewires have been previously cleared with a total guidewire length of 200 cm in K183608 and K192783, respectively. This additional length does not impact any features or dimensions at the distal end of the guidewire and does not raise new questions of safety and effectiveness.

NON-CLINICAL PERFORMANCE TESTS

Biocompatibility

Biocompatibility testing was conducted for the reference devices (K222347, K173235). These results support the biocompatibility of the subject devices because they use the same materials, processes, components, and dimensions within the range of the previously cleared predicate and reference devices. The evaluation supports that the subject device with its accessories meets biological safety requirements per ISO 10993-1:2018 for externally communicating medical devices with circulating blood contact for a limited duration (less than 24 hours).

Sterilization

The subject devices have been adopted into a validated sterilization cycle that uses 100% EO to achieve a sterilization assurance level (SAL) of 10^{-6}.

Bench Performance Testing

The bench performance testing conducted for the reference devices (K222347, K173235) and the predicate 200 cm long models of the subject guidewires cleared under K183608 and K192783, support the performance of the subject devices (300 cm) because they use the same materials, processes, components, and dimensions within the range of the previously cleared predicate and reference devices.

Following the risk assessments conducted in accordance with ISO 14971, no additional testing was deemed necessary to support the substantial equivalence of the subject device models.

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