January 26, 2023

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

Re: K222437
Trade/Device Name: Aristotle Colossus Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: December 28, 2022
Received: December 29, 2022

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 (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
OHT5: Office of Neurological
and Physical Medicine 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)*

K222437

Device Name
Aristotle Colossus Guidewire

Indications for Use *(Describe)*
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.

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
(Per 21 CFR 807.92)

SCIENTIA VASCULAR, INC.
Aristotle Colossus Guidewire

Submitter Name and Address:
Scientia Vascular, Inc.
3487 West 2100 South Suite 100
West Valley City, UT 84119

Contact Person: Max Alfonso
Regulatory Affairs Specialist
Phone: 1 (888) 385-9016
Email: regulatory@scientiavascular.com

Date Prepared: January 26, 2023

Trade Name:	Aristotle Colossus Guidewire
Common Name:	Guidewire
Classification Name:	Guide, Wire, Catheter, Neurovasculature per 21 CFR 870.1330
Primary Product Code:	MOF
Secondary Product Code:	DQX
Review Panel:	Neurology
Device Class:	Class II device per 21 CFR 870.1330
Predicate Device:	Aristotle 24 Guidewire (K192783)
Reference Device:	ASAHI Neurovascular Guide Wire ASAHI CHIKAI Black 18 (K141751)

DEVICE DESCRIPTION

Scientia Vascular's Aristotle Colossus Guidewire is a modification of Scientia Vascular's Aristotle 24 Guidewire. It is a 0.035" diameter, steerable guidewire with a shapeable tip to aid in accessing vasculature. The guidewire is supplied sterile and is for single use only. It is provided in a single stiffness profile (standard) and is available in a range of lengths from 150 cm to 300 cm.
The distal portion of the guidewire tip includes a radiopaque platinum wire marker coil to facilitate fluoroscopic visualization. The guidewire has a hydrophilic polymer coating on the distal portion and a polytetrafluoroethylene (PTFE) coating on the proximal portion to reduce friction during manipulation in tortuous vessels.

The guidewire is provided with a shaping mandrel, an introducer (to aid with the insertion of the

guidewire into a catheter hub and/or a rotating hemostasis valve (RHV)), and a torque device (to attach to the proximal portion of the guidewire to facilitate gripping and manipulation of the guidewire during use). The shaping mandrel, introducer, and torque device accessories are included to facilitate use of the guidewire and are not intended to contact the patient's body.

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.

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Aristotle Colossus Guidewire has the:

- Same indications for use,
- Same intended use,
- Same operating principle,
- Same basic guidewire design,
- Same materials, and
- Same packaging materials and sterilization process,

as the predicate device.

Shown in the table below is the comparison of technological characteristics for the Aristotle Colossus Guidewire to those of the predicate device, Aristotle 24 Guidewire (K192783), and the reference device, ASAHI Neurovascular Guide Wire ASAHI CHIKAI Black 18 (K141751).

Table 1: Comparison between Subject & Predicate/Reference Device Technological Characteristics Note: Differences between subject and predicate devices are **bolded**			
Description	Subject Device Aristotle Colossus Guidewire	Predicate Device Aristotle 24 Guidewire (K192783)	Reference Device ASAHI Neurovascular Guide Wire ASAHI CHIKAI Black 18 (K141751)
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 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.	This guide wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guide wire is intended for use only in the neuro 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 Aristotle 24 Guidewire is intended for use by a physician to help introduce and position catheters or other interventional devices within the neuro and peripheral vasculature.	This guide wire is intended to be used in the neuro vasculature to facilitate the placement and exchange of therapeutic devices such as cerebral catheters during intravascular therapy. This guide wire is intended for use only in the neuro vasculature.
Wire Diameter	**0.035" (0.88 mm)**	0.024" (0.61 mm)	0.018” (0.45 mm)
Device Length	**150 cm to 300 cm**	200 cm	200 cm
Flex Length	35 cm	35 cm	34 cm
Tip Type and Shape	Straight, shapeable	Straight, shapeable	Round Curve
Flexibility	Standard	Support, Standard, Soft	Standard
Wire Material	Core wire: Stainless-steel	Core wire: Stainless-steel	Core wire: Stainless-steel
Coatings	Distal End: Hydrophilic	Distal End: Hydrophilic	Distal End: Hydrophilic

Table 1: Comparison between Subject & Predicate/Reference Device Technological Characteristics Note: Differences between subject and predicate devices are **bolded**			
Description	Subject Device Aristotle Colossus Guidewire	Predicate Device Aristotle 24 Guidewire (K192783)	Reference Device ASAHI Neurovascular Guide Wire ASAHI CHIKAI Black 18 (K141751)
	Distal Coated Length: 46 cm	Distal Coated Length: 46 cm	Distal Coated Length: 170 cm
	Proximal End: PTFE	Proximal End: PTFE	Proximal End: None
Accessories	Shaping mandrel, guidewire introducer, torque device	Shaping mandrel, guidewire introducer, torque device	Shaping mandrel, guidewire introducer, torque device
Packaging Configuration	Tyvek pouch, carton, shipper box	Tyvek pouch, carton, shipper box	Tyvek pouch, carton, shipper box
Sterilization Method	100% Ethylene Oxide (EO)	100% EO	100% EO
Shelf Life	**1 year**	3 years	3 years

The subject device has the following technological characteristic differences when compared to the predicate device: wire diameter, device length and shelf life. The changes in technological characteristics do not result in new materials used or raise new or different questions of safety and effectiveness, nor do the changes result in introduction of new risks for the subject device.

NON-CLINICAL PERFORMANCE TESTS

Results of tests performed on the Aristotle Colossus Guidewire demonstrate that it met the test acceptance criteria and meets the requirements of relevant standards and FDA guidance documents.

Biocompatibility

The biocompatibility evaluation for the subject device, Aristotle Colossus Guidewire, identified as an externally communicating device with circulating blood contact for a limited duration (≤ 24 hours), was performed in accordance with ISO 10993-1: 2018. The materials used in the manufacture of the subject device Aristotle Colossus Guidewire are identical to those used in the manufacturing of the predicate device Aristotle 24 Guidewire, also manufactured by Scientia Vascular, Inc. (K192783). Therefore, some testing is adopted from K192783. The following are the biocompatibility tests performed on the Aristotle Colossus Guidewire:

Table 2: Summary of Subject Device Biocompatibility Testing Performed.

Name of Test	Test Summary	Conclusion of Testing
Cytotoxicity: MEM Elution	Cell culture was observed for cytotoxic reactivity.	Non-cytotoxic.
Direct Contact and Extract Method Hemolysis Test	The difference between the hemolytic indexes of the subject device and the negative control was evaluated.	Non-hemolytic.
Partial Thromboplastin Time (PTT) Test	The clotting time was observed for both the subject device and the predicate.	No effect on the PTT. The two samples are considered similar.
Complement Activation of SC5b-9	Comparison of the subject device SC5b-9 value to the predicate device for all exposure times was performed.	The subject device had similar or lower potential to activate the complement system when compared to the predicate.
Hemocompatibility In- vitro Blood Loop	The catheters are placed in an in- vitro blood loop for three runs. The thrombus score for the subject device and predicate device is observed.	Thrombogenic risk potential similar to the predicate.

Functional Testing

Performance testing on the subject device was performed after conducting a risk assessment in accordance with ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices. Functional testing was performed in accordance with the following standards:

- ISO 11070-2014 – Sterile Single-use Intravascular Introducers, Dilators, and Guidewires;
- AAMI TIR42:2021 – Evaluation of Particulates Associated with Vascular Medical Devices;

as well as the FDA Guidance Documents:

- Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling (October 2019);
- Intravascular Catheters, Wires and Delivery Systems with Lubricious Coatings – Labeling

Considerations (October 2019).

Table 3 summarizes the testing performed to demonstrate substantial equivalence of the subject device to the predicate device.

Table 3: Summary of Subject Device Functional Testing		
Test	Test Method Summary	Results
Dimensional Verification	Tests per ISO 11070: Dimensional inspection per engineering drawings.	The Aristotle Colossus Guidewires met test acceptance criteria.
Tensile Strength	Tensile testing per ISO 11070.	The Aristotle Colossus Guidewires met test acceptance criteria
Fracture and Flexing	Fracture and Flexing tests per ISO 11070.	The Aristotle Colossus Guidewires met test acceptance criteria
Torqueability and Torque Strength	Measurement of torque response (average input to output lag) in an anatomical model. Torque turns to failure in an anatomical model.	The Aristotle Colossus Guidewires met test acceptance criteria
Tip Flexibility	Measure force to deflect guidewire tips at 5 mm, 10 mm, and 20 mm test lengths.	The Aristotle Colossus Guidewires met test acceptance criteria
Tip Shape, Retention	Guidewires must be shapeable and must retain shaped angle after simulated use.	The Aristotle Colossus Guidewires met test acceptance criteria
Coating Lubricity and Durability	Frictional force of coated guidewires was determined after simulated use in a tortuous path.	The Aristotle Colossus Guidewires met test acceptance criteria
Coating Integrity	Coating uniformity and integrity were visually examined on dyed samples after simulated use in a tortuous path.	The Aristotle Colossus Guidewires met test acceptance criteria
Particulate	Particulates of various size ranges counted after simulated use in a tortuous path.	The Aristotle Colossus Guidewires met test acceptance criteria
Simulated Use Model Testing and Product Compatibility	Anatomical model designed to simulate the tortuous anatomy of the neurovasculature was used for simulated use testing and product compatibility.	The Aristotle Colossus Guidewires met test acceptance criteria
Usability Evaluation	Physicians evaluated subject and predicate guidewires for various performance characteristics in a human cadaver.	The Aristotle Colossus Guidewires met test acceptance criteria

Sterilization

The Aristotle Colossus Guidewire was evaluated for shelf-life testing, packaging integrity, and sterilization including testing to ensure sterilization assurance levels (SAL) of at least 10^{-6}, and testing for EO and ethylene chlorohydrin (ECH) residuals and bacterial endotoxin levels.

CONCLUSION

The subject device, Aristotle Colossus Guidewire, has the same intended use, same indications for use, and the same fundamental design, materials, and 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, Aristotle 24 Guidewire.