October 30, 2019

Scientia Vascular LLC
Amy McManus
Regulatory Affairs Manager
3487 West 2100 South, Suite 100
West Valley City, Utah 84119

Re: K192783
Device Name: Aristotle 24 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: September 24, 2019
Received: September 30, 2019

Dear Amy McManus:

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,

Xiaolin Zheng, Ph.D.
Director (*Acting*)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192783

Device Name
Aristotle 24 Guidewire

Indications for Use *(Describe)*
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

(PER 21 CFR 807.92)

SCIENTIA VASCULAR LLC

Special 510(K): Device Modification
Aristotle 24 Guidewire

510(k) Sponsor:	Scientia Vascular LLC 3487 West 2100 South Suite 100 West Valley City, UT 84119 Tel: (888) 385.9016
Contact Person:	Amy McManus, Regulatory Affairs Manager Tel: (888) 385.9016 E-mail: amcmanus@scientiavascular.com
Date Prepared:	September 13, 2019

Subject Device Information:

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 18 Guidewire (K183608)

DEVICE DESCRIPTION

The Aristotle 24 Guidewire is a modification of Scientia Vascular's Aristotle 18 Guidewire. It is a 0.024" 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 range of stiffness profiles: soft, standard, and support. The product is provided in one overall length of 200cm.

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 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 hemostasis valve) and a torque device (to attach to the proximal portion to facilitate gripping and manipulation of the guidewire during use). The mandrel, introducer and torque accessory devices are included to facilitate use of the guidewire and are not intended to contact the patient's body.

The Aristotle 24 Guidewire is substantially equivalent with respect to technological characteristics, design and materials to the previously cleared Aristotle 18 Guidewire.

INDICATION FOR USE

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 is the same indication for use as previously cleared for the Aristotle 18 Guidewire, K183608.

INTENDED USE

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.

TECHNOLOGICAL CHARACTERISTICS

The Aristotle 24 Guidewire has the following similarities to the previously cleared Aristotle 18 Guidewire:

- Both devices have the same indicated use,
- Both devices have the same intended use
- Both devices use the same operating principle,
- Both devices incorporate the same basic guidewire design,
- Both devices incorporate the same materials, and

- Both devices are packaged and sterilized using the same materials and processes.

The technological characteristic comparison of the subject and predicate device is summarized in Table 1 below.

Table 1:Comparison between Subject & Predicate Device Technological Characteristics: Note: Areas of difference will be indicated in RED		
Characteristic	Subject Device Aristotle 24 Guidewire	Predicate Aristotle 18 Guidewire (K183608)
Anatomical Location	Neuro and peripheral vasculature	Neuro and peripheral vasculature
Dimensions	*Max O.D.:* **0.024" (0.61mm)** *Length:* 200cm	*Max O.D.:* 0.018" (0.46mm) *Length:* 200cm
Core Wire	Stainless Steel	Stainless Steel
Distal Tip	Shapeable *Length:* 35cm *Material:* Nitinol	Shapeable *Length*: 35cm *Material:* Nitinol
Stiffness Profiles	Range from support (stiff), standard (middle) to soft (flex)	Range from support (stiff), standard (middle) to soft (flex)
Coatings	*Distal End:* Hydrophilic *Proximal* End: PTFE	*Distal End:* Hydrophilic *Proximal End:* PTFE
Radiopaque Marker	Radiopaque marker at distal tip	Radiopaque marker at distal tip
Centering Coil	**Two (2)** Centering coil	One (1) Centering coil
Bushing	**One**	None
Shaping Mandrel (Accessory)	Provided with each guidewire	Provided with each guidewire
Guidewire Introducer (Accessory)	Provided with each guidewire	Provided with each guidewire
Torque Device (Accessory)	Provided with each guidewire	Provided with each guidewire
Sterilization Method	100% Ethylene Oxide (EO)	100% Ethylene Oxide (EO)

The subject device, Aristotle 24, has three technological characteristic differences when compared to the predicate device. The changes in technological characterists do not result in new materials used or new questions of safety or effectiveness, nor do they result in new risks for the subject device. Testing of the subject device has been performed, demonstrating the safety and effectiveness of the device.

NON-CLINICAL PERFORMANCE TESTS

Biocompatibility

The materials used in the manufacture of the subject device Aristotle 24 Guidewire are identical to those used in the manufacturing of the predicate device Aristotle 18 Guidewire also manufactured by Scientia Vascular LLC, cleared March 22, 2019 after review of K183608. Biocompatibility testing was completed for the Aristotle 24 and consisted of the following tests:

- In-vitro Blood Flow Thrombogenicity Study
- MEM elution
- Toxicological risk assessment
- ASTM Hemolysis (direct contact and extract)
- Partial Thromboplasting Time, and
- Compliment Activation

Sterilization

100% EO is used to sterilize the device to achieve a SAL of at least 10^{-6}. The device was adopted into an EO sterilization processing group in accordance with AAMI TIR 28:2016. Completion of the review performed to the requirements of AAMI TIR 28:2016 indicate the Aristotle 24 and the Aristotle 18 are similar with regards to all device and packaging characteristics that could affect the ability to sterilize the devices.

Functional Testing

Performance testing on the subject device was performed after conducting a risk assessment in accordance with *EN ISO 14971:2012 Medical Devices – Risk Management*. Functional testing was performed in accordance with ISO 11070:2014 *Sterile single-use intravascular introducers, dilators and guidewires* and the FDA Guidance Document *Coronary and Cerebrovascular Guidewire Guidance* (January 1995). Table 2 summarizes the functional tests performed and test results obtained to demonstrate substantial equivalence to the predicate device:

Table 2:Summaries of Functional Tests Conducted to Support this Premarket Notification for the Modified (Subject) Device, Aristotle 24 Guidewire		
Test	Test Method Summary	Results
Dimensional Verification	Tests per ISO 11070: Dimensional inspection per engineering drawings.	The Aristotle 24 Guidewires met testing acceptance criteria.
Tensile Strength	Tensile testing per ISO 11070.	The Aristotle 24 Guidewires met testing acceptance criteria
Flexing Test	Tests per ISO 11070: Inspection for defects and damage or flaking of the coating after flexing.	The Aristotle 24 Guidewires met testing acceptance criteria
Fracture	Tests per ISO 11070: Inspection for fracture, loosening, or failure after wrapping around mandrel.	The Aristotle 24 Guidewires met testing acceptance criteria
Torqueability	Measurement of torque response (average input to output lag) in an anatomical model.	The Aristotle 24 Guidewires met testing acceptance criteria
Torque Strength	Torque turns to failure in an anatomical model.	The Aristotle 24 Guidewires met testing acceptance criteria
Tip Flexibility	Measure force to deflect guidewire tips to 45 and 90 degrees at 5mm, 10mm, and 20mm test lengths.	The Aristotle 24 Guidewires met testing acceptance criteria
Tip Shape, Retention	Guidewires must be shapeable and must retain shaped angle after simulated use.	The Aristotle 24 Guidewires met testing acceptance criteria
Particulate	Particulates of various size ranges counted after simulated use in a tortuous path.	The Aristotle 24 Guidewires met testing acceptance criteria
Coating Lubricity and Durability	Frictional force of coated guidewires was determined after simulated use in a tortuous path.	The Aristotle 24 Guidewires met testing acceptance criteria
Coating Integrity	Coating uniformity and integrity visually examined on dyed samples after simulated use in a tortuous path.	The Aristotle 24 Guidewires met testing acceptance criteria
Simulated Use Model Testing and Product Compatibility	Anatomical model designed to simulate the tortuous anatomy of the neurovasculature used for simulated use testing	The Aristotle 24 Guidewires met testing acceptance criteria
Usability Evaluation	Physicians evaluated subject and predicate guidewires for various performance characteristics in a human cadaver.	The Aristotle 24 Guidewires met testing acceptance criteria

CONCLUSION:

Scientia Vascular, LLC has presented information in this premarket notification supporting the Aristotle 24 Guidewire is substantially equivalent with respect to technological characteristics and indications for use to the predicate device.