January 22, 2018

Scientia Vascular LLC
% Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K173235
Trade/Device Name: Aristotle 14 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: December 13, 2017
Received: December 14, 2017

Dear Mark Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*

K173235

Device Name

Aristotle 14 Guidewire

Indications for Use *(Describe)*

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.

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 LLC
ARISTOTLE 14 GUIDEWIRE

510(k) Sponsor: Scientia Vascular LLC
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Date Prepared: December 8, 2017

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Trade Name:	Aristotle 14 Guidewire
Common Name:	Guidewire
Classification Name	Catheter Guide Wire per 21 CFR 870.1330
Product Code:	DQX
Predicate Device:	PVS 1300 Synchro® 0.014" Guidewire (K032146)

DEVICE DESCRIPTION

The Scientia Vascular Aristotle 14 Guidewire is a 0.014" 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, from soft to support. The product is provided in 200cm and 300cm lengths.

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 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 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 14 guidewire is substantially equivalent with respect to technological characteristics, design and materials to Boston Scientific - Precision Vascular's currently marketed PVS 1300 Synchro® 0.014" Guidewire cleared under K032146. Both devices are provided with a torque device and introducer.

INDICATIONS FOR USE

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 indications for use statement is equivalent to that of the predicate device and the differences in wording are not critical to the intended therapeutic, diagnostic, prosthetic, surgical or other use of the device. The differences do not affect the safety and effectiveness of the device when used as labeled, as the same intent is documented for the predicate and new devices.

TECHNOLOGICAL CHARACTERISTICS

As shown in the table below, the technological characteristics of the Aristotle 14 Guidewire are equivalent to those of the predicate device, the PVS 1300 Synchro® 0.014" Guidewire.

Comparison between Subject & Predicate Device Technological Characteristics			
Characteristic	**Subject Device Aristotle 14 Guidewire**	**PVS 1300 Synchro® 0.014" Guidewire (K032146)**	**Comparison**
Anatomical Location	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
Dimensions	***O.D.:*** 0.014" (0.36mm) ***Length:*** 200cm to 300cm range	***O.D.:*** 0.014" (0.36mm) ***Length:*** 180cm to 300cm range, with 200cm being typical	Equivalent
Core Wire	Stainless Steel	Stainless Steel	Same
Distal Tip	Shapeable ***Length:*** 35cm ***Material****:* Nitinol	Shapeable ***Length:*** 25cm to 65cm range, with 35 to 45cm being typical ***Material:*** Nitinol	Equivalent
Stiffness Profiles	Range from support (stiff) to flex (soft)	Range from support (stiff) to flex (soft)	Equivalent
Coatings	***Distal End:*** Hydrophilic ***Proximal End:*** PTFE	***Distal End:*** Hydrophilic ***Proximal End:*** PTFE	Equivalent
Radiopaque Marker	1 radiopaque marker at distal tip	1 radiopaque marker at distal tip	Same
Introducer (Accessory)	Provided with each guidewire	Provided with each guidewire	Equivalent
Torque Device (Accessory)	Provided with each guidewire	Provided with each guidewire	Same
Sterilization Method	100% Ethylene Oxide (EO)	Currently radiation sterilization [devices originally cleared were sterilized with100% Ethylene Oxide (EO)]	Same

Results of tests performed on the new Aristotle 14 Guidewire demonstrate that the new guidewire performs as well as the predicate device and/or meets requirements of relevant standards. Further, any differences in technological characteristics of the Aristotle Guidewires when compared with predicate device characteristics do not raise different questions of safety and effectiveness.

NON-CLINICAL PERFORMANCE TESTS

Biocompatibility

Biocompatibility of the Aristotle 14 Guidewire and accessory materials has been verified in accordance with ISO 10993-1:2009 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and FDA's Guidance for Industry and Food and Drug Administration Staff *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued June 16, 2016.

The results of the following biological and toxicological safety evaluations verified the biocompatibility of the subject device when tested as an external communicating, blood contact, limited duration (≤24 hours) device:

- Cytotoxicity;
- Sensitization;
- Irritation/Intracutaneous Reactivity;
- Acute Systemic Toxicity;
- Materials-Mediated Pyrogenicity;
- Hemocompatibility
    - Hemolysis by Direct Contact and Extract;
    - Partial Thromboplastin Time (PTT);
    - Complement Activation of C3a and SC5b-9;
    - Thrombogenicity in a Dog Model; and
- Latex Antigenic Protein Content

Results of these tests are summarized in the following table.

Summaries of Biocompatibility Tests Conducted to Support this Premarket Notification		
Test	**Results**	**Conclusions**
Cytotoxicity [L-929 MEM Elution]	Cell culture treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic

Summaries of Biocompatibility Tests Conducted to Support this Premarket Notification		
Test	**Results**	**Conclusions**
Sensitization [Maximization (Magnusson-Kligman)]	Challenge sites treated with test sample exhibited no erythema or edema (Grade 0).	Negative for dermal sensitization
Irritation [Intracutaneous Toxicity (ISO)]	The mean test score in 0.9% Normal Saline extract was 0, and in Sesame Oil was 0.1.	Non-irritating
Systemic Toxicity (Acute) [Systemic Injection (ISO)]	No study animals were observed with abnormal clinical signs indicative of toxicity during the 72-hour test period.	Non-toxic
Systemic Toxicity (Acute) [Material Mediated Pyrogen in a Rabbit Model]	Temperature increases for the all test animals did not exceed the acceptable test limit for maximum individual temperature rise.	Non-pyrogenic
Hemocompatibility [Hemolysis, direct contact - device/material (human blood)]	The difference between the hemolytic indices of the test article and the negative control was 0.00%.	Non-hemolytic
Hemocompatibility [Hemolysis, indirect – device/material (human blood)]	The difference between the hemolytic indices of the test article and the negative control was 0.00%.	Non-hemolytic

Summaries of Biocompatibility Tests Conducted to Support this Premarket Notification		
Test	**Results**	**Conclusions**
Hemocompatibility [Partial Thromboplastin Time (PTT test) - Human plasma]	Both the subject device and predicate device fell within the same thrombogenicity category (minimal activator)	Subject and predicate devices showed similar thrombogenicity.
Hemocompatibility [Complement Activation - SC5b-9]	Amounts of SC5b-9 generated by the test article and predicate device after exposure times of 30 and 60 minutes were not statistically different. The amount of SC5b-9 generated by the test article was statistically lower than that released by the predicate after 90 minutes exposure.	Subject and predicate devices showed similar complement system activation.
Hemocompatibility [Thrombogenicity in a Dog Model]	Both test animals had a subject device (Aristotle 14 Guidewire) and predicate device (Synchro-14 Guidewire) inserted. The average thrombus score was the same for both the subject and predicate device.	Subject and predicate devices showed similar thrombogenic potential.
Latex [LEAP test]	No Latex Antigenic Proteins were detected.	Contains no detectable traces of latex

Functional Testing

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). The following table summarizes the functional tests performed and test results obtained to demonstrate substantial equivalence to the predicate device:

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Visual Inspection	Tests per ISO 11070: Visual inspection for extraneous matter, process and surface defects or defects that may cause trauma to vessels during use	No extraneous matter, surface defects or visible droplets of coating were present on the Aristotle 14 Guidewires.
Dimensional Verification	Tests per ISO 11070: Dimensional inspection per engineering drawings	All guidewires met dimensional specifications.
Flexing Test	Tests per ISO 11070: Inspection for defects and damage or flaking of the coating after flexing	No defects or damage / flaking of the coating were observed after flexing.
Tensile Strength	Tensile testing per ISO 11070	All guidewires met minimum force breakage requirements specified in ISO 11070.
Tip Shape, Retention	Guidewires must be shapeable and must retain shaped angle after simulated use	All tips met shaping and shape retention requirements after simulated use.
Torqueability	Measurement of torque response (average input to output lag) in an anatomical model	All guidewires demonstrated acceptable torque responses. The torque response of the subject device was comparable to that of the predicate device.
Torque Strength	Torque turns to failure in an anatomical model	All guidewires demonstrated acceptable torque strength. The torque strength of the subject device was comparable to that of the predicate device.

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Tip Flexibility	Measure force to deflect guidewire tips to 45 and 90 degrees at 5mm, 10mm, and 20mm test lengths	The forces required to deflect the guidewire tips were acceptable. The flexibility of the tips of all subject devices was comparable to the tip flexibility of the predicate guidewire.
Fracture	Tests per ISO 11070: Inspection for fracture, loosening, or failure after wrapping around mandrel	No guidewires showed signs of fracture, loosening, or failure after wrapping them 8 times around a mandrel.
Coating Lubricity and Durability	Frictional force of coated guidewires was determined after simulated use in a tortuous path	All guidewires met specified frictional force requirements.
Coating Integrity	Coating uniformity and integrity visually examined on dyed samples after simulated use in a tortuous path	All samples showed acceptable coating coverage after simulated use.
Particulates	Particulates of various size ranges counted after simulated use in a tortuous path	A comparable number of particulates was recovered from subject and predicate devices following simulated use.
Torque Device - Introducer Testing	Various tests on guidewire accessories per ISO 11070: biocompatibility, visual inspection, corrosion resistance, tensile testing, luer taper dimensions, pouch seal strength	Acceptance criteria of all tests were met.
Simulated Use Model Testing and Product Compatibility	Anatomical model designed to simulate the tortuous anatomy of the neurovasculature used for simulated use testing	Guidewires and predicate devices were found to perform acceptably in evaluations of: Torqueability in tortuous vasculature, Lubricity, Microcatheter Support & Tracking, Compatibility with Introducer, Compatibility with Torque Device, and Compatibility with Microcatheter

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Cadaver Testing	Physicians evaluated subject and predicate guidewires for various performance characteristics in a human cadaver	Subject and predicate guidewires both exhibited acceptable performance.
Radiopacity	Subject and predicate guidewires evaluated by physicians in human cadaver	Both subject and predicate guidewires exhibited acceptable radiopacity.
Corrosion Resistance	Test for corrosion resistance per ISO 11070	There were no signs of corrosion on guidewires after soaking in typical end-use solutions.
Chemical Compatibility	Guidewires were exposed to saline and contrast agent/saline solutions and examined for degradation.	All guidewires showed no signs of degradation, corrosion or physical decomposition after exposure.
MRI Compatibility	Guidewires are constructed of metallic materials and should not be exposed to MRI procedures.	No testing performed. Aristotle Guidewires are labeled “MRI Unsafe.”
Latex	Tested for trace latex proteins per ASTM D6499-07	No detectable traces of latex were found.
Package Integrity	Simulated transportation test per ASTM D 4169:16. Pouch evaluated for seal strength per ASTM F 88-15 and leak tests (bubble test) per ASTM F 2096-11	Following exposure to typical storage and transportation conditions, all sterile barrier pouches maintained their integrity and labeling remained affixed and legible.
Shelf Life	Device performance attributes that can be affected by storage conditions were evaluated after exposure to accelerated aging conditions per ASTM F1980.	After exposure to accelerated aging conditions simulating real-time storage under ambient conditions for 6 months, all device performance acceptance criteria were met, justifying labeling the devices with a 6-month shelf life.

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Sterilization Validation	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 28:2009. Validation of the EO sterilization cycle was performed using the Half-cycle, overkill approach described in Section B.1.2 of ISO11135:2007 Annex B.	Results justified adoption into the EO sterilization processing group: Comparative and Bioburden Resistance study results demonstrated that PCDs are more difficult to sterilize than devices; Bioburden Enumeration and Extraction Efficiency tests were used to enumerate the CFUs present on devices; and Bacteriostasis/ Fungistasis test results demonstrated that the product does not inhibit the growth of organisms.
Sterilization Validation: EO and ECH Residuals	Measured EO and ECH residuals per AAMI/ANSI/ISO 10993-7	The residual traces of EO and ECH remaining in the Aristotle 14 Guidewire after exposure to the EO sterilization process are well below the limits specified in ISO 10993-7.
Sterilization Validation: Bacterial Endotoxin Levels	LAL testing was conducted in accordance with ANSI/AAMI ST72:2011/(R)2016, USP <161>, and USP <85>, using the kinetic chromogenic method.	< 2.15 EU/device

CONCLUSION:

Scientia Vascular, LLC has presented information in this premarket notification supporting its contention that the Aristotle 14 Guidewire is substantially equivalent with respect to technological characteristics and indications for use to the predicate device.