August 7, 2018

Scientia Vascular LLC
David Sabodski
Director of Quality Assurance
3487 West 2100 South Suite 100
West Valley City, Utah 84119

Re: K181828
Trade/Device Name: Volo 14 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: July 9, 2018
Received: July 10, 2018

Dear David Sabodski:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Xiaolin Zheng -S

for 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)*
K181828

Device Name
Volo 14 Guidewire

Indications for Use *(Describe)*
The Volo 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.

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

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510(K) SUMMARY

(Per 21 CFR 807.92)

SCIENTIA VASCULAR LLC

Special 510(K): Device Modification
Volo 14 Guidewire

510(k) Sponsor: Scientia Vascular LLC
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Contact Person: David Sabodski, Director of Quality Assurance
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Date Prepared: July 31, 2018

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Trade Name:	Volo 14 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 14 Guidewire (K173235)

DEVICE DESCRIPTION

The Volo 14 Guidewire is a modification of Scientia Vascular's Aristotle 14 Guidewire. It 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 standard. 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 Volo 14 Guidewire is substantially equivalent with respect to technological characteristics, design and materials to the previously cleared Aristotle 14 Guidewire.

INDICATIONS FOR USE

The Volo 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.

This is the same indications for use as previously cleared for the Aristotle 14 Guidewire, K173235

TECHNOLOGICAL CHARACTERISTICS

The Volo 14 Guidewire has the following similarities to the previously cleared Aristotle 14 Guidewire:

- Both devices have the same indicated use,
- Both devices use the same operating principle,
- Both devices incorporate the same basic guidewire design,
- Both Devices incorporate the same materials,
- Both devices have the same shelf life, and
- Both devices are packaged and sterilized using the same materials and processes.

Comparison between Subject & Predicate Device Technological Characteristics			
Characteristic	**Subject Device Volo 14 Guidewire**	**Predicate Aristotle 14 Guidewire (K173235)**	**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:*** 200cm to 300cm range	Same
Core Wire	Stainless Steel	Stainless Steel	Same
Distal Tip	Shapeable ***Length:*** 35cm ***Material****:* Nitinol	Shapeable ***Length:*** 35cm ***Material****:* Nitinol	Same
Stiffness Profiles	Range from standard (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

Comparison between Subject & Predicate Device Technological Characteristics			
Characteristic	**Subject Device Volo 14 Guidewire**	**Predicate Aristotle 14 Guidewire (K173235)**	**Comparison**
Sterilization Method	100% Ethylene Oxide (EO)	100% Ethylene Oxide (EO)	Same

The only difference between Volo 14 Guidewires and Aristotle 14 Guidewires is in the construction of the guidewire tips. The cut profile of the Nitinol tip in the Volo 14 Guidewire has been modified to slightly chnage the flexibility of the tip.

The Volo 14 Guidewires will be supplied with a blue torque device, whereas the Aristotle 14 Guidewires are supplied with a green torque device. Both torque devices are supplied by Merit Medical and have the same 510(k) approval, K936032.

NON-CLINICAL PERFORMANCE TESTS

Biocompatibility

The materials used in the manufacture of the subject Volo 14 Guidewire are identical to those used in the manufacture of the Aristotle 14 Guidewire also manufactured by Scientia Vascular LLC, cleared January 22, 2018 after review of K173235; in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

Consequently, no additional evaluations are needed to determine that the subject guidewires present a low and acceptable biological and toxicological risk when used in accordance with their intended and indicated uses, and no additional information is provided in this 510(k).

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 Volo 14 and the Aristotle 14 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). 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 for the Modified (Subject) Device, Volo 14 Guidewire		
Test	**Test Method Summary**	**Results**
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 Volo 14 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 Volo 14 Guidewires demonstrated acceptable torque strength. The torque strength of the subject device was comparable to that of the predicate device.
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 Volo 14 Guidewire tips were acceptable. The flexibility of the tips of all subject devices was comparable to the tip flexibility of the predicate guidewire.
Simulated Use Model Testing and Product Compatibility	Anatomical model designed to simulate the tortuous anatomy of the neurovasculature used for simulated use testing	Volo 14 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

CONCLUSION:

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