September 26, 2018

Access Scientific, LLC
Ms. Martina Nguyen
Regulatory Affairs & Quality Assurance Specialist
3910 Sorrento Valley Boulevard, Suite 200
San Diego, California 92121

Re: K181563
Trade/Device Name: The ARTERIAL WAND Safety Introducer with Arterial Catheter made of ChronoFlex C with BioGUARD Technology
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY, DYB
Dated: August 24, 2018
Received: August 27, 2018

Dear Ms. Nguyen:

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,

Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000979673, cn=Finn E. Donaldson -S
Date: 2018.09.26 15:36:30 -04'00'

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181563

Device Name
ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology

Indications for Use *(Describe)*
The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is used to gain access to the vascular (e.g. arterial) system to sample blood, administer fluids, and monitor blood pressure intravascularly.

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

The following 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. SUBMITTER INFORMATION

Company Name:	Access Scientific, LLC
Company Address:	3910 Sorrento Valley Boulevard Suite 200 San Diego, CA 92121
Company Phone:	(858) 259-8333
Company Facsimile:	(858) 259-5298
Contact Person:	Martina Nguyen Regulatory Affairs & Quality Assurance Specialist mnguyen@accessscientific.com
Date:	September 25, 2018

2. PROPOSED DEVICE IDENTIFICATION

Trade Name:	The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology
Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous
Classification Regulation:	21 CFR 870.1250
Device Class:	Class II
Product Code(s):	DQY, DYB
Advisory Panel:	Cardiovascular

3. PREDICATE DEVICE IDENTIFICATION

The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is substantially equivalent to the following predicate device:

- K171146 – Arrow Seldinger Arterial Catheterization Device

4. REFERENCE DEVICE IDENTIFICATION

The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is substantially equivalent to the following reference devices:

- K162322 – The POWERWAND™ Safety Introducer with an Extended Dwell Catheter
- K052564 – Leaderflex

5. DEVICE DESCRIPTION

The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is an all-in-one preassembled device that combines the functionality of a catheter introducer system with an arterial catheter. The ARTERIAL WAND™ is used to gain access to the vascular (e.g. arterial) system to insert the arterial catheter. The arterial catheter may then be left in place for a period of <30 days, used to sample blood, administer fluids, and monitor blood pressure intravascularly.

The ARTERIAL WAND™ catheter has been proven in vitro to be 100% as accurate as a steel cannula and in vivo to be more accurate in assessing mean arterial pressure than a competitive polyurethane catheter (Arrow 4020 Radial Artery Catheter, Arrow International, Inc.).[1]

[1]Clinical correlation to in vivo animal testing and in vitro testing has not been ascertained.

The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology pre-assembled device includes the following components:

- Introducer Needle
- Guidewire
- Dilator Hub
- Catheter made of ChronoFlex C® with BioGUARD™ Technology

The ARTERIAL WAND™ is sterile, single-use (<30 days) intravascular catheter. It is used to gain access to the vascular (e.g. arterial) system.

6. INDICATION FOR USE

The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is used to gain access to the vascular (e.g. arterial) system to sample blood, administer fluids, and monitor blood pressure intravascularly.

7. TECHNOLOGICAL CHARACTERISTICS

The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is substantially equivalent to the predicate device's technological characteristics in terms of overall performance.

The difference between the proposed device and the predicate device is the catheter material, ChronoFlex C® with BioGUARD™ Technology and Polyether Block Amide respectively. The catheter material of the proposed device is equivalent to the reference device, the POWERWAND™ Safety Introducer with an Extended Dwell Catheter (hereafter POWERWAND™), also manufactured by Access Scientific and previously cleared for commercial distribution under 510(k) K162322. The performance data was leveraged from the reference device, the POWERWAND™, which is similar to the proposed device except for a different effective catheter length, and has substantially equivalent performance.

The proposed device indications for use to gain access to the vascular system to sample blood and administer fluids share the same indications for use as the reference device, the POWERWAND™. In addition, the proposed device indications for use to gain access to the vascular system to monitor blood pressure intravascularly share the same indications for use as the reference device, the Leaderflex, manufactured by Vygon and previously cleared for commercial distribution under 510(k) K052564.

Table 1 provides a comparison of the features between the ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology to the predicate device and the reference devices.

Table 1: Comparison Feature between the Proposed, Predicate, and Reference Devices				
Technological Characteristics	**Proposed Device**	**Predicate Device (K171146)**	**Reference Device (K162322)**	**Reference Device (K052564)**
Trade name	The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology	Arrow Seldinger Arterial Catheterization Device	The POWERWAND™ Safety Introducer with an Extended Dwell Catheter	Vygon Leaderflex
Classification Name	Catheter, percutaneous	Catheter, percutaneous	Introducer, Catheter	Catheter, Intravascular, Therapeutic, Short-Term Less Than 30 Days
Classification Regulation	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1340	21 CFR 880.5200
Product Code	DQY	DQY	DYB	FOZ
Indications for Use	The ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is used to gain access to the vascular (e.g. arterial) system to sample blood, administer fluids, and monitor blood pressure intravascularly.	The Arrow Seldinger Arterial Catheterization Device permits access to the peripherical arterial circulation or to other small vessels.	The POWERWAND™ Safety Introducer with an Extended Dwell Catheter is used to gain access to the vascular system to sample blood and administer fluids intravenously. It may be used for power injection of contrast media up to a rate of 8 ml/sec and at a maximum of 325 psi fluid pressure.	The primary indications of the Leaderflex catheter is pressure monitoring in peripheral arteries. The device may also be used for venous access in pediatric patients.
Mechanism of Action	"all-in-one" preassembled device that combines the functionality of a catheter introducer system with an arterial catheter	preassembled device that combines the functionality of a catheter introducer system with an arterial catheter	"all-in-one" preassembled device that combines the functionality of a catheter introducer system with an extended dwell catheter	Suitable for a variety of venous and arterial applications in adults and children: • Central venous catheterization • Arterial catheterization

Table 1: Comparison Feature between the Proposed, Predicate, and Reference Devices				
Technological Characteristics	**Proposed Device**	**Predicate Device (K171146)**	**Reference Device (K162322)**	**Reference Device (K052564)**
				• Peripheral venous catherization
Principle of Operation	Seldinger Technique	Seldinger Technique	Seldinger Technique	Seldinger Technique
Catheter Material	ChronoFlex C® with BioGUARD™ Technology	Polyether Block Amide	ChronoFlex C® with BioGUARD™ Technology	Polyurethane
Components	• Introducer Needle • Guidewire • Dilator Hub • Catheter made of ChronoFlex C® with BioGUARD™ Technology	• Introducer Needle or Catheter over Needle assembly • Spring wire guide • Catheter assembly with extension tube segment with side clamp, and luer hub with dust cap	• Introducer Needle • Guidewire • Dilator Hub • Catheter made of ChronoFlex C® with BioGUARD™ Technology	• Catheter • Guidewire • Needle
Introducer Needle Gauge	21 gauge	18 gauge 20 gauge 22 gauge 24 gauge	21 gauge 24 gauge	21 gauge
Catheter Effective Length	5 cm	2.5 – 23 cm	6 cm	4 – 20 cm
Guidewire Outer Diameter	0.46 mm	18 gauge: 0.64 mm 20 gauge: 0.53 mm 22 gauge: 0.53 mm 24 gauge: 0.46 mm	21 gauge: 0.46 mm 24 gauge: 0.30 mm	0.7 mm
Introducer Method	Introducer needle	Introducer needle and Introducer catheter-over-needle	Introducer Needle	Introducer Needle
Sterilization Method	Ethylene oxide method	Ethylene oxide method	Ethylene oxide method	–
Shelf-life	2 years	2 years	2 years	–
Packaging	PETG tray with Tyvek® lid	PET/LDPE film mated with Tyvek®	PETG tray with Tyvek® lid	–

8. SUMMARY OF TESTING

Design verification testing was conducted to demonstrate that the performance characteristics of the ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology, is equivalent to the predicate device and satisfy the requirements of the product design specification for its intended use.

Performance data was leveraged from the reference device, the POWERWAND™, because the fundamental scientific technology of the ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is the same as the POWERWAND™ with the exception of the catheter effective length. Therefore, performance testing was only conducted on the modified component. Refer to **Table 2** for a summary of the design verification tests performed.

Table 2: Design Verification Testing of the ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology

Component	Testing
Introducer Needle	• Strength of union between needle hub and needle tube • Resistance to breakage
Catheter	• Collapse pressure • Column strength • Flowrate • Force at break • Priming volume • Burst pressure • Freedom from leakage
Device System	• Axial Forces • Fast-flash™ evaluation • Insertability • Needle-stick safety • Intraluminal positioning visual indicators • Particulate Matter content

9. CONCLUSIONS

The results from testing demonstrate that the ARTERIAL WAND™ Safety Introducer with Arterial Catheter made of ChronoFlex C® with BioGUARD™ Technology is substantially equivalent to the predicate device in design, function, and indications for use.