September 18, 2018

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

Re: K182243
Trade/Device Name: The CVC WAND Safety Introducer with Valved Peelable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 16, 2018
Received: August 20, 2018

Dear Martina 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,

Misti L. Malone -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182243

Device Name
The CVC WANDSafety Introducer with Valved Peelable Sheath

Indications for Use *(Describe)*
The CVC WAND Safety Introducer with Valved Peelable Sheath is indicated for use in percutaneous insertion of catheters into the venous system.

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

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:	August 16, 2018

2. PROPOSED DEVICE IDENTIFICATION

Trade Name:	The CVC WAND™ Safety Introducer with Valved Peelable Sheath
Common Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
Classification Regulation:	21 CFR 870.1340
Device Class:	Class II
Product Code(s):	DYB
Advisory Panel:	Cardiovascular

3. PREDICATE DEVICE IDENTIFICATION

The CVC WAND™ Safety Introducer with Valved Peelable Sheath is substantially equivalent to the following Access Scientific device, which is cleared for commercial distribution under 510(k) K131148:

Trade Name:	The CVC WAND™ Safety Introducer with Valved Peelable Sheath

Common Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
Classification Regulation:	21 CFR 870.1340
Device Class:	Class II
Product Code(s):	DYB
Advisory Panel:	Cardiovascular

4. DEVICE DESCRIPTION

The CVC WAND™ Safety Introducer with Valved Peelable Sheath (hereafter CVC WAND™) is a catheter introducer device that is virtually identical to the predicate device, the CVC WAND™ Safety Introducer with Valved Peelable Sheath, cleared for commercial distribution under 510(k) K131148. When assembled for use, it is an all-in-one preassembled intravascular catheter introducer, that provides the clinician with a simple and accelerated approach to the Seldinger Technique for placing in-dwelling intravascular catheters. The device is composed of the following key components:

- Introducer Needle
- Guidewire
- Dilator
- Valved Peelable Sheath Introducer

The CVC WAND™ includes a 21-gauge microaccess needle, nylon tissue dilator, FEP peelable sheath and Nitinol guidewire. This device has an integrated valve within the body of the Peelable Sheath Introducer hub which is designed to reduce inflow of air into the bloodstream and outflow of blood when the guidewire, introducer needle and dilator are removed, but it is not a hemostasis valve. The device also has a blood flashback window proximal to the needle's tip which allows the clinician to observe blood flashback upon entering the vessel with the Safety Introducer. The microaccess needle is echogenic and provides the pathway for the guidewire insertion, while the dilator facilitates placement of the peelable sheath and ultimately catheter placement.

The CVC WAND™ is individually packaged in a PETG, glycol modified polyethylene terephthalate, plastic tray. The tray is heat sealed with a Tyvek® lid. The device is provided 'STERILE' (ethylene oxide gas) and is for 'single-use' only.

5. INDICATION FOR USE

The CVC WAND™ Safety Introducer with Valved Peelable Sheath is indicated for use in percutaneous insertion of catheters into the venous system.

6. TECHNOLOGICAL CHARACTERISTICS

The CVC WAND™ has equivalent technological characteristics as the predicate devices in terms of components, design, and performance. The Needle, Guidewire, and Dilator are the same components used in the predicate device. The Valved Peelable Sheath Introducer component is equivalent to the predicate device with the exception of the valve subcomponent found within the hub to reduce the risk of blood and air intake during the catheterization procedure. The valve subcomponent is manufactured with a new material, thermoplastic elastomer, rather then the existing silicone material.

7. SUMMARY OF TESTING

A program with designed verification testing, including biocompatibility testing, was conducted to demonstrate the biological safety and biomechanical performance characteristics of the CVC WAND™.

The only device modification was to the Valved Peelable Sheath Introducer component. The modification was a material change to the valve found within the hub of the Valve Peelable Sheath Introducer component. The material of the valve changed from silicone to thermoplastic elastomer. Therefore, biocompatibility testing of this component with the new material was conducted in accordance with the provisions of ISO 10993-1:2009 and summarized in **Table 4.1**. The results of the biocompatibility testing satisfied the acceptance criteria of the relevant ISO 10993 standards.

Table 4.1: Biocompatibility Testing of the Valved Peelable Sheath Introducer Component

Test	Test Method/Standard
Cytotoxicity	ISO MEM Elution Using L-929 Mouse Fibroblast Cells (GLP) ISO 10993-5:2009
Sensitization	ISO Guinea Pig Maximization Sensitization Test (GLP – 2 Extracts) ISO 10993-10:2010
Intracutaneous Reactivity	ISO Intracutaneous Irritation Test (GLP – 2 Extract) ISO 10993-10:2010
Acute Systemic Toxicity	USP Systemic Injection (Normal Saline and Cottonseed Oil Extract) ISO 10993-11:2006
Hemolysis	ASTM Hemolysis Assay – Direct Contact and Extract Method (GLP) ISO 10993-4:2002
Material Mediated Pyrogenicity	Normal Saline Extract ISO 10993-11:2006
Partial Thromboplastic Time (PTT)	Direct Contact

Table 4.1: Biocompatibility Testing of the Valved Peelable Sheath Introducer Component	
Test	**Test Method/Standard**
	ISO 10993-4:2002
In Vitro Platelet and Leucocyte Counts	Direct Contact ISO 10993-4:2002
Complement Activation	C3a and Sc5b-9 Complexes ISO 10993-4:2002

Some design verification performance testing was leveraged from the predicate device manufactured by Access Scientific and are summarized in **Table 4.2.** These specific performance testing were leveraged from the predicate device, cleared for commercial distribution under 510(k) K131148, because these performance criteria of the device were not affected as a result of the material change.

Prospective design verification performance testing conducted for the device modification of CVC WAND™ is shown in **Table 4.3.** The results of the design verification performance testing satisfy acceptance criteria identified in applicable standards and/or the device design specification.

Table 4.2: Prior Applicable Testing Conducted on the Predicate Device (K131148)	
Component	**Testing**
Introducer Needle	• Lumen patency • Tensile strength: tube-to-hub bond • Air leak/resistance to stress cracking • Corrosion resistance
Dilator	• Distal Tip Columnar Strength • Strength of Union: Tube-to-Hub
Guidewire	• Fracture testing • Flex testing • Strength of union: core-to-coil • Strength of union: wire-to-cap • Corrosion resistance
Valved Peelable Sheath Introducer	• Distal Tip Columnar Strength • Strength of Union: Tube-to Hub, Valve-to-Lower-Hub • Split/Feel Force of Hub/Sheath
Device System	• Axial Forces • "Fast-Flash™" Evaluation • Insertability • Needle-stick safety • Guidewire cap snap-on force

Table 4.2: Prior Applicable Testing Conducted on the Predicate Device (K131148)	
Component	**Testing**
	• Protective Cover Removal Force – Dilator, Sheath Introducer • Needle Cover Functional Evaluation and Removal Force • Needle Cover Silicone Migration Evaluation • Needle lock to Needle hub separation force

Table 4.3 Prospective Testing Conducted on the CVC WAND™ Safety Introducer with Valved Peelable Sheath	
Component	**Testing**
Valved Peelable Sheath Introducer	• Valve Air Leakage • Valve Liquid Leakage • Valve Flexibility • Valve Patency • Valve Integrity
Device System	• Particulate Matter USP <788> (Reference only)

8. CONCLUSIONS

The test results demonstrate that the device modifications to the CVC WAND™ Safety Introducer with Valved Peelable Sheath is substantially equivalent to the predicate devices in design, function, and indications for use.