July 25, 2019

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

Re: K183066
Trade/Device Name: The POWERWAND Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C with BioGUARD Technology-3 Fr, 4 Fr, and 5 Fr Model
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 11, 2019
Received: June 12, 2019

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/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,

For

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183066

Device Name
The POWERWAND Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C with BioGUARD Technology-3 Fr, 4 Fr, and 5 Fr Model

Indications for Use *(Describe)*
The POWERWAND Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C with BioGUARD Technology 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.

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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K183066

510(K) SUMMARY

1.0 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 Fax:	(858) 259-5298
Contact Person:	Martina Nguyen Sr. Manager Quality & Regulatory Affairs mnguyen@accessscientific.com
Date:	July 25, 2019

2.0 PROPOSED DEVICE IDENTIFICATION

Trade Name:	The POWERWAND™ Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C® with BioGUARD™ Technology-3 Fr, 4 Fr, and 5 Fr Model
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

3.0 PREDICATE DEVICE IDENTIFICATION

The POWERWAND™ Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C® with BioGUARD™ Technology has the following predicate device:

- K162322 – POWERWAND™ Safety Introducer with an Extended Dwell Catheter, 3 Fr Model

4.0 REFERENCE DEVICE IDENTIFICATION

The POWERWAND™ Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C® with BioGUARD™ Technology has the following reference device:

- K131300 – POWERWAND™ Safety Introducer with an Extended Dwell Catheter, 4 Fr and 5 Fr Model

5.0 DEVICE DESCRIPTION

The POWERWAND™ Safety Introducer with an Extended Dwell 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 extended dwell (< 30 days) Intravenous (IV) Catheter. It is intended to provide the clinician with a safe, simple and accelerated approach using the Accelerated Seldinger Technique. The POWERWAND™ is used to gain access to the vascular system to insert the IV Catheter. The IV Catheter may then be left in place for a period of < 30 days and used to sample blood and administer fluids intravenously. It may also be used to power inject contrast media up to a rate of 8 ml/sec and at a maximum of 325 psi fluid pressure. The device incorporates a mechanism that provides passive needle stick safety.

The POWERWAND™ Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C® with BioGUARD™ Technology has shown in vivo to be thromboresistant with respect to both thrombus on the surface of the catheter and thrombus on the wall of the vein, based upon 72-hour canine jugular vein thromboresistance studies. This pre-clinical in vivo evaluation does not necessarily predict clinical performance with respect to thrombus formation.

6.0 INDICATIONS FOR USE

The POWERWAND™ Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C® with BioGUARD™ Technology 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.

7.0 TECHNOLOGY CHARACTERISTICS

The POWERWAND™ Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C® with BioGUARD™ Technology has the same technological characteristics as the predicate device in terms of components, materials, chemical composition, and design. However, the subject device includes a new thrombogenicity labeling claim.

8.0 SUMMARY OF TESTING

A series of pre-clinical thrombogenicity tests were conducted to support a thrombogenicity labeling claim.

Design verification performance testing was leveraged from the predicate device and the reference device manufactured by Access Scientific. The performance criteria of the device were not affected as a result of the addition of the labeling claim.

9.0 CONCLUSIONS

The test results demonstrate that the POWERWAND™ Safety Introducer with an Extended Dwell Catheter made of ChronoFlex C® with BioGUARD™ Technology – 3 Fr, 4 Fr, and 5 Fr Model is substantially equivalent to the predicate device in design, function, and indications for use.