November 17, 2016

Access Scientific, LLC
Mr. Walter Cordiglia
Senior Director, Quality Engineering and Regulatory Affairs
3910 Sorrento Valley Blvd., Suite 200
San Diego, California 92121

Re: K162322
Trade/Device Name: POWERWAND Safety Introducer with an Extended Dwell Catheter, 3 Fr. Model
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 19, 2016
Received: September 20, 2016

Dear Mr. Cordiglia:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K162322

Device Name
The POWERWAND® Safety Introducer with an Extended Dwell Catheter (3 Fr Model)

Indications for Use (Describe)
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.

Type of Use (Select one or both, as applicable)

- [x] 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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“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

11.1 SUBMITTER INFORMATION
A. Company Name: Access Scientific, LLC.
B. Company Address: 3910 Sorrento Valley Blvd., Suite 200
San Diego, CA 92121
C. Company Phone: (858) 480-0216
D. Company Facsimile: (858) 259-5298
E. Contact Person: Walter Cordiglia
Sr. Director of Quality Engineering and Regulatory Affairs
wcordiglia@accessscientific.com
F. Date Summary Prepared: November 17, 2016

11.2 DEVICE IDENTIFICATION
A. Device Trade Name: the POWERWAND® Safety Introducer with an Extended Dwell Catheter (3 Fr Model)
B. Common Name: Catheter Introducer
Intravascular Catheter, Therapeutic, Short-term
C. Classification Name(s): Introducer, Catheter
D. Classification Regulation(s): 21 CFR 870.1340
E. Device Class: Class II
F. Product Code: DYB
G. Advisory Panel: Cardiovascular

11.3 IDENTIFICATION OF PREDICATE DEVICE
The predicate device is the POWERWAND® Safety Introducer with an Extended Dwell Catheter (4 & 5 Fr Models) that were cleared for commercial distribution under 510(k) K131300.

The NovaCath™ Secure IV Catheter System cleared for commercial distribution under 510(k) K160374 was used as reference device as part of this submission.

11.4 DEVICE DESCRIPTION
The POWERWAND® Safety Introducer with an Extended Dwell Catheter is an all-in-one preassembled intravascular catheter introducer with intravascular catheter that consists of the
following principle components: Introducer Needle, Guidewire, Dilator and an Extended Dwell Catheter. It is intended to provide the clinician with a safe, simple and accelerated approach, using the Accelerated Seldinger Technique, to place an in-dwelling intravascular catheter through the skin into the circulatory system. The Extended Dwell Catheter allows for withdrawal of blood and the administration of fluids, including power injection of contrast media. The device also incorporates a mechanism that provides passive needle stick safety.

11.5 INDICATIONS FOR USE

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.

11.6 TECHNOLOGICAL CHARACTERISTICS

The proposed modified device has the same technological characteristics as the predicate device in terms of components, materials, chemical composition, and design. The changes to the device impact the axial dimensions of the components required to create a 3 Fr Model of the device, modifying (reducing) the effective length of the IV Catheter and adding different foam inserts in the final device packaging. Performance testing has been conducted to confirm that the modified device satisfies performance requirements.

11.7 SUMMARY OF TESTING

Design verification testing was conducted to demonstrate that the performance characteristics of the modified POWERWAND® Safety Introducer with an Extended Dwell Catheter (3 Fr Model) is equivalent to the predicate devices and satisfy the requirements of the product design specification for its intended use.

Prospective testing conducted for the 3 Fr Model POWERWAND® is shown in Table 11.1.

<table>
<thead>
<tr>
<th>Component</th>
<th>Testing</th>
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</thead>
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| 24 Gauge Needle | • Strength of union between needle hub and needle tube  
| | • Resistance to Breakage |
| Dilator | • Dilator Column Strength  
| | • Strength of Union (Hub to Tube) |
| 3 Fr IV Catheter – Standard Testing | • Collapse Pressure  
| | • Catheter Column Strength  
| | • Flowrate  
| | • Catheter Force at Break  
| | • Priming Volume |

Table 11.1: Prospective Testing of the 3 Fr POWERWAND®

Access Scientific, LLC.
the POWERWAND® Safety Introducer with an Extended Dwell Catheter (3 Fr Model)
510(k) Premarket Notification
<table>
<thead>
<tr>
<th>Component</th>
<th>Testing</th>
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<tbody>
<tr>
<td>• Burst Pressure</td>
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<tr>
<td>• Freedom from Leakage</td>
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<tr>
<td>3 Fr IV Catheter – Testing after Pre-Conditioning</td>
<td>• Chemical Compatibility</td>
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<tr>
<td></td>
<td>• Bending Fatigue</td>
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<tr>
<td></td>
<td>• Power Injection</td>
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<tr>
<td></td>
<td>• Burst Pressure</td>
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<tr>
<td>Introducer System</td>
<td>• Axial Forces</td>
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<td></td>
<td>• Fast-flash™ Evaluation</td>
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<td></td>
<td>• Insertability</td>
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<td>• Needle-Stick safety</td>
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<td>• Intraluminal Positioning Visual Indicators</td>
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<td></td>
<td>• PM Content</td>
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</tbody>
</table>

### 11.8 CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the modified POWERWAND® Safety Introducer with an Extended Dwell Catheter (3 Fr Model) is substantially equivalent to the predicate device (4 & 5 Fr Models) in design, function, and indications for use.