510(K) SUMMARY

5.1 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) 259-8333
D. Company Facsimile:	(858) 259-5298
E. Contact Person:	Albert Misajon Chief Compliance Officer amisajon@the-wand.com
F. Date:	April 22, 2013

SEP 0 4 2013

5.2 DEVICE IDENTIFICATION

A. Device Trade Name:	the CVC WAND™ Safety Introducer with Valved Peelable Sheath
B. Common Name:	Catheter Introducer
C. Classification Name(s):	Introducer. Catheter
D. Classification Regulation(s):	21 CFR 870.1340
E. Device Class:	Class II
F. Product Code(s):	DYB
G. Advisory Panel:	Cardiovascular

5.3 IDENTIFICATION OF PREDICATE DEVICES

The CVC WAND™ Safety Introducer with Valved Peelable Sheath is substantially equivalent to the following devices, which are cleared for commercial distribution in the United States:

- The PICC WAND® Peelable Safety Introducer manufactured by Access Scientific and cleared for commercial distribution under 510(k) K111138
- The AirGuard™ Valved Introducer manufactured by Bard Access Systems, Inc. and cleared for commercial distribution under 510(k) K042036

5.4 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 PICC WAND® Peelable Safety Introducer (K111138). When assembled for use, it is an all-in-one preassembled intravascular catheter introducer, that provides the clinician with a safe, 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

Some of the components of the predicate device have been modified to facilitate the specific clinical requirements for peripheral access for the placement of a Central Venous Catheter (CVC). The primary modification to the predicate device is the addition of a valve within the body of the Peelable Sheath Introducer Hub. When the Guidewire, Needle and Dilator are removed from the Valved Peelable Sheath Introducer, as part of performing the Accelerated Seldinger Technique procedure, the valve in the hub is actuated (in the closed position) thus preventing air from entering into the venous circulatory system and conversely preventing blood from leaking out. The valve is designed to allow passage of the CVC through it into the central venous circulatory system. This valve provides a similar function as the Bard AirGuard™ Valved Introducer, the other predicate device (K042036). After confirmation of the proper CVC placement, the Valved Peelable Sheath Introducer is removed by breaking apart the Sheath Introducer hub and peeling the sheath off the CVC in the identical manner as the predicate PICC WAND® Peelable Sheath Introducer.

The CVC WAND™ Safety Introducer 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.

5.5 INDICATIONS FOR USE

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

5.6 TECHNOLOGICAL CHARACTERISTICS

The CVC WAND™ Valved Safety Introducer with Valved Peelable Sheath has equivalent technological characteristics as the predicate devices in terms of components, materials, design, and performance. The Needle is the same component as is used in the predicate PICC WAND® Peelable Safety Introducer. The Guidewire is manufactured from the same materials and has the same outside diameter as that used in the predicate PICC WAND® Peelable Safety Introducer. The length of the Guidewire has been shortened to be compatible with the dimensional characteristics of the new device. The Dilator is

manufactured from equivalent materials as the predicate PICC WAND® Peelable Safety Introducer and has been modified in dimensional characteristics to make it compatible with the Valved Peelable Sheath Introducer. The Valved Peelable Sheath Introducer component is equivalent to the Sheath Introducer of the predicate devices in materials and dimensions. and incorporates a valve in the hub to reduce the risk of blood loss and air intake during the catheterization procedure.

5.7 SUMMARY OF TESTING

A program of design verification testing, including biocompatibility testing and *in vitro* bench testing, was conducted to demonstrate the biological safety and biomechanical performance characteristics of the CVC WAND™ Safety Introducer with Valved Peelable Sheath.

The Valved Peelable Sheath Introducer is the only component that contains materials not previously included in the predicate devices. Biocompatibility testing of this component was conducted in accordance with the provisions of ISO 10993-1:2009. This testing is summarized in **Table 5.1.** The results of all biocompatibility testing satisfied the acceptance criteria of the relevant ISO 10993 standards.

TABLE 5.1: BIOCOMPATIBILITY TESTING OF THE VALVED PEELABLE SHEATH INTRODUCER COMPONENT

Test	Test Method/Standard
Cytotoxicity	ISO Elution ISO 10993-5:2009
Sensitization	ISO Maximization ISO 10993-10:2010
Intracutaneous Reactivity	ISO Intracutaneous Reactivity ISO 10993-10:2010
Acute Systemic Toxicity	USP Systemic Injection ISO 10993-11:2006
Hemolysis – Direct Contact	ISO10993-4:2002 Direct Contact
Material Mediated Pyrogenicity	ISO 10993-11:2006 Rabbit Pyrogen Test
In Vivo Thrombogenicity	ISO 10993-4:2002 4-Hour Thromboresistance in Dogs
Partial Thromboplastin Time	ISO 10993-4:2002
In Vitro Platelet and Leucocyte Counts	ISO 10993-4:2002
Complement Activation	ISO 10993-4:2002 Using Both C3a and SC5b-9

Design verification performance testing leveraged from previously cleared predicate devices by Access Scientific is summarized in **Table 5.2.** Prospective testing conducted for the CVC WAND™ Safety Introducer with Valved Peelable Sheath is shown in **Table 5.3.** The results of design verification performance testing satisfy acceptance criteria as identified in applicable standards and the device design specification.

TABLE 5.2: PRIOR APPLICABLE TESTING CONDUCTED ON PREDICATE DEVICES MANUFACTURED BY ACCESS SCIENTIFIC

Component	Testing	Applicable Access Scientific 510(k)
21-Gauge Needle	• Lumen patency • Tensile strength: tube-to-hub bond • Air leak/resistance to stress cracking • Corrosion resistance	K081697
0.018" Guidewire	• Fracture testing • Flex testing • Strength of union: core-to-coil • Strength of union: wire-to-cap • Corrosion resistance	K093022 K111138
Introducer System	• Needle-stick safety • Guidewire cap snap-on force • Needle lock to Needle hub separation force	K081697

TABLE 5.3: PROSPECTIVE TESTING CONDUCTED ON THE CVC WAND™ SAFETY INTRODUCER WITH VALVED PEELABLE SHEATH.

Component	Testing
Dilator	• Distal Tip Columnar Strength • Strength of Union: Tube-to-Hub
Valved Peelable Sheath Introducer	• Distal Tip Columnar Strength • Strength of Union: Tube-to-Hub, Valve-to-Lower-Hub • Split/Peel Force of Hub/Sheath • Valve Flexibility/Patency • Valve Integrity • Valve Liquid Leakage • Valve Air Leakage
Introducer System	• Axial Forces • "Fast-flash™" Evaluation • Insertability • Protective Cover Removal Force – Dilator, Sheath Introducer • Needle Cover Functional Evaluation and Removal Force • Needle Cover Silicone Migration Evaluation • Particulate Matter

5.8 CONCLUSIONS DRAWN FROM STUDIES

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 4, 2013

Access Scientific, LLC
C/O Albert Misajon
3910 Sorrento Valley Blvd. Suite 200
San Diego, CA 92121 US

Re: K131148
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: July 29, 2013
Received: July 30, 2013

Dear Mr. Misajon:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

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: To Be Assigned By FDA [K131148]

Device Name: the CVC WAND™ Safety Introducer with Valved Peelable Sheath

Indications for Use:

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)