K101422

# 510(K) SUMMARY

MAR 2 2 2011

## 5.1 Submitter Information

| | | |
|---|---|---|
| A. | Company Name: | Access Scientific, Inc. |
| B. | Company Address: | 12526 High Bluff Drive, Suite 360<br>San Diego, CA 92130 |
| C. | Company Phone: | (858) 259-8333 |
| D. | Company Facsimile: | (858) 259-5298 |
| E. | Contact Person: | Albert Misajon<br>Vice President, Regulatory Affairs and Quality Assurance<br>amisajon@the-wand.com |
| F. Date: | | January 20, 2011 |

## 5.2 Device Identification

| | |
|---|---|
| A. Device Trade Name: | the Power WAND™ Safety Introducer with an Extended Dwell Catheter |
| B. Common Name: | Catheter Introducer, Intravascular Catheter |
| C. Classification Name(s): | Catheter Introducer<br>Catheter, Intravascular, Therapeutic, Short-Term, < 30 Days |
| D. Classification Regulation(s): | 21 CFR 870.1340<br>21 CFR 880.5200 |
| E. Device Class: | Class II |
| F. Product Code(s): | DYB, FOZ |
| G. Advisory Panel: | General Hospital |

## 5.3 Identification of Predicate Devices

The Power WAND™ Safety Introducer with an Extended Dwell Catheter is substantially equivalent to the following devices, which are cleared for commercial distribution in the United States:

- The WAND™ MicroAccess Safety Introducer manufactured by Access Scientific and cleared for commercial distribution under 510(k) (K081697)
- The PICC WAND™ Peelable Safety Introducer manufactured by Access Scientific, Inc. and cleared for commercial distribution under 510(k) K093022

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- The Introcan Safety® IV Catheter manufactured by B. Braun Medical, Inc. and cleared for commercial distribution under 510(k) K020785
- The BD OneCath™ manufactured by Becton Dickinson Infusion Therapy Systems, Inc. and cleared for commercial distribution under 510(k) K042862

## 5.4 Device Description

The Power WAND™ Safety Introducer with an Extended Dwell Catheter is an all-in-one pre-assembled device that combines the functionality of a catheter introducer system with an extended dwell (> 72 hours but < 30 days) intravenous (IV) Catheter. The Power WAND™ Safety Introducer with an Extended Dwell Catheter 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 can also be used to power inject contrast media up to a rate of 5 cc/sec. at a maximum of 300 psi fluid pressure.

The Power WAND™ Safety Introducer with an Extended Dwell Catheter is provided "STERILE" by ethylene oxide gas and is labeled "Nonpyrogenic" and for "Single-Use".

The device is composed of the following components:

- Needle
- Guidewire
- Dilator
- Extended Dwell IV Catheter

The Power WAND™ Safety Introducer with an Extended Dwell Catheter accesses the target vessel using the Accelerated Seldinger Technique (AST). Once the IV Catheter is positioned within the target circulatory vessel the Needle/Guidewire/Dilator are removed from the patient as a single unit. The remaining indwelling single-lumen IV Catheter is used to sample blood and administer fluids intravenously for a time period of < 30 days. It can also be used to power inject contrast media up to a rate of 5 cc/sec at a maximum fluid pressure of 300 psi. A catheter stabilization device, StatLock IV Ultra®, is provided as an accessory to securely anchor the IV Catheter in place during use.

## 5.5 Indications for Use

The Power WAND™ Safety Introducer with an Extended Dwell Catheter is used to gain access to the vascular system to sample blood and administer fluids intravenously. May be used for power injection of contrast media at a rate of 5cc/sec at up to 300 psi fluid pressure.

## 5.6 Technological Characteristics

The Power WAND™ Safety Introducer with an Extended Dwell Catheter has the same technological characteristics as the predicate devices in terms of components, materials, chemical composition, and design. The Needle and Guidewire are the same components as those used in the predicate PICC WAND™ Peelable Safety Introducer. The Dilator is

manufactured from the same materials as the predicate PICC WAND™ Peelable Safety Introducer and has only been modified in minor dimensional characteristics to make it fully compatible with the IV Catheter. The extended dwell IV Catheter is manufactured from slightly different materials and has different length than the predicate Introcan Safety® IV Catheter. Biocompatibility testing and *in vitro* performance testing has demonstrated that the IV Catheter materials are non-toxic and that the IV Catheter performance characteristics satisfy performance requirements of the product specification and are equivalent to the predicate device.

## 5.7 Summary of Testing Performed

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 Power WAND™ Safety Introducer with an Extended Dwell Catheter.

Biocompatibility testing conducted is summarized in **Table 5.1.** All materials satisfied the acceptance criteria of the biocompatibility testing.

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TABLE 5.1: BIOCOMPATIBILITY TEST PROGRAM

| | Test | Test Method/Standard |
|---|---|---|
| 1 | Cytotoxicity | ISO MEM Elution<br>ISO 10993-5:2009 |
| 2 | Sensitization | ISO 10993-10:2002<br>(Saline and Cottonseed Oil Extracts) |
| 3 | Intracutaneous Reactivity | ISO 10993-10:2002<br>(Saline and Cottonseed Oil Extracts) |
| 4 | Acute Systemic Toxicity | ISO 10993-11:2006<br>(Saline and Cottonseed Oil Extracts) |
| 5 | Hemolysis – Direct Contact | ISO10993-4:2002<br>(Direct Contact) |
| 6 | Hemolyis - Extract | ISO10993-4:2002<br>(Phosphate Buffered Saline Extract) |
| 7 | Material Mediated Pyrogenicity | ISO 10993-11:2006<br>(Saline Extract) |
| 8 | *In Vivo* Thrombogenicity | ISO 10993-4:2002<br>(Direct Contact) |
| 9 | Complement Activation | ISO 10993-4:2002<br>(C3a and SC5b-9 Complexes) |
| 10 | Genotoxicity: Bacterial Reverse Mutation (Ames) | ISO 10993-3:2003<br>(Saline and PEG extracts) |
| 11 | Genotoxicity: *In Vitro* Mouse Lymphoma | ISO10993-3:2003<br>(Saline and PEG Extracts) |
| 12 | Genotoxicity: *In Vivo* Mouse Micronucleus | ISO10993-3:2003<br>(Saline and Cottonseed Oil Extracts) |
| 13 | Subchronic Intravenous Toxicity | ISO 10993-11:2006<br>(Saline Extract) |
| 14 | Subacute Intraperitoneal Toxicity | ISO 10993-11:2006<br>(Cottonseed Oil Extract) |
| 15 | Subcutaneous Implant | ISO 10993-6:2007<br>(Direct Contact) |

Performance characteristic testing was conducted to evaluate the performance requirements of the Power WAND™ Safety Introducer with an Extended Dwell Catheter. Testing leveraged from the previously cleared predicate devices is summarized in **Table 5.2.**

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TABLE 5.2: PRIOR APPLICABLE TESTING CONDUCTED FOR THE PREDICATE DEVICES MANUFACTURED BY ACCESS SCIENTIFIC, INC.

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

Prospective testing of the Dilator included the following testing:

- Distal tip columnar strength
- Strength of union: tube-to-hub

Prospective testing of the IV Catheter included the following testing:

- Collapse Pressure
- Distal tip columnar strength
- Catheter Flow Rate
- Tensile Strength
- Priming Volume
- Catheter Burst Pressure
- Catheter-Hub Gauging
- Catheter-Hub Liquid Leakage
- Catheter-Hub Air Leakage
- Catheter-Hub Separation Force
- Catheter-Hub Stress Cracking
- Catheter-Hub Unscrewing Torque
- Catheter-Hub Ease of Assembly

- Catheter-Hub Resistance to Overriding
- Infusion Induced Catheter Movement

Prospective testing of the IV Catheter following "worst-case" pre-conditioning included the following:

- Visual Inspection
- Fatigue Testing
- Power Injection
- Catheter Elongation
- Catheter Burst Pressure

Prospective testing of the integrated Power WAND™ Safety Introducer with an Extended Dwell Catheter included the following:

- Catheter Hub- StatLock IV Ultra® Securement Device Separation Force
- Dilator to Catheter Fit-up
- Dilator Hub-Catheter Hub Removal Torque
- Dilator Hub-Catheter Hub Separation Force
- Axial Forces
- Fast-flash Evaluation
- Introducer System Insertability
- Needle Cover Removal Force
- Needle to Dilator Fit-up

Test results indicate that the device satisfies all performance requirements for its intended use.

## 5.8 Conclusions Drawn from Studies

The results of testing demonstrate that the Power WAND™ Safety Introducer with an Extended Dwell Catheter 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Albert Misajon
Vice President, Regulatory Affairs
12526 High Bluff Drive
Suite 2360
San Diego, CA 92130

MAR 2 2 2011

Re: K101422
Trade/Device Name:
Regulation Number: 21 CFR 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 11, 2011
Received: March 14, 2011

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

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 K101422

**Device Name:** the Power WAND™ Safety Introducer with an Extended Dwell Catheter

**Indications for Use:**

The Power WAND™ Safety Introducer with an Extended Dwell Catheter is used to gain access to the vascular system to sample blood and administer fluids intravenously. May be used for power injection of contrast media at a rate of 5cc/sec at up to 300 psi fluid pressure.

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 (ONE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101422