

510(K) SUMMARY

AUG 13 2010

11.1 SUBMITTER INFORMATION

- A. Company Name: Access Scientific, Inc.
- B. Company Address: 12526 High Bluff Drive, Suite 360
San Diego, CA 92130
- C. Company Phone: (858) 259-8333
- D. Company Facsimile: (858) 259-5298
- E. Contact Person: Albert Misajon
Vice President, Regulatory Affairs and
Quality Assurance
amisajon@the-wand.com
- F. Date Summary Prepared: April 22, 2010

11.2 DEVICE IDENTIFICATION

- A. Device Trade Name: the PICC WAND™ Peelable Safety Introducer
- 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: DYB
- G. Advisory Panel: Cardiovascular

11.3 IDENTIFICATION OF PREDICATE DEVICE

The predicate device is the PICC WAND™ Peelable Safety Introducer that was cleared for commercial distribution under 510(k) K093022.

11.4 DEVICE DESCRIPTION

The PICC WAND™ Peelable Safety Introducer is an all-in-one preassembled intravascular catheter introducer that consists of the following basic introducer components: Introducer Needle, Nitinol Guidewire, Dilator and a peelable Sheath Introducer. 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 peelable Sheath Introducer allows for the placement of peripherally inserted central catheters (PICC) and midline catheters. The device includes a Fast-flash™ feature that provides the clinician with feedback that the introducer needle is in the

intraluminal position within the blood vessel. The device also incorporates a safety mechanism to guard against accidental needle stick.

11.5 INDICATIONS FOR USE

The PICC WAND™ Peelable Safety Introducer is used to facilitate the placing of an intravascular catheter through the skin into the circulatory system.

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 only changes to the device are in the path of blood flow through the device to implement the Fast-flash™ feature of the device, and the addition of a 5 Fr model. In the predicate device the blood flowed through windows in the Needle and the Dilator and was observed between the Dilator and the Sheath Introducer. In the modified device the blood flows through a window in the Needle and is observed between the Needle and the Dilator. Performance testing has been conducted to verify that the visual indicators and timing of the blood flow is equivalent or superior to the predicate device, and that the 5 Fr model satisfies performance characteristics required to accommodate a 5 Fr PICC or midline catheter.

11.7 PERFORMANCE TESTING

Design verification testing was conducted to demonstrate that the performance characteristics of the modified PICC WAND™ Peelable Safety Introducer are equivalent to the predicate device and satisfy the requirements of the product design specification for its intended use. This testing included the following *in vitro* bench testing:

- Dilator – Distal/tip columnar strength
- Dilator – Tensile strength of union (tube to hub)
- Sheath Introducer – Distal/tip columnar strength
- Sheath Introducer – Tensile strength of union (tube to hub)
- System insertability
- System – Intraluminal visual indicators
- System – Fast-flash function and timing
- Shelf life (accelerated aging) to labeled expiration date

11.8 CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the PICC WAND™ Peelable Safety Introducer is substantially equivalent to the predicate device in design, function, and indications for use.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

AUG 13 2010

Mr. Albert Misajon
Vice President, Regulatory Affairs and Quality Assurance
Access Scientific, Inc.
12526 High Bluff Drive, Suite 360
San Diego, CA 92130

Re: K101150
Trade Names: PICC WAND™ Peelable Safety Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 16, 2010
Received: July 19, 2010

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

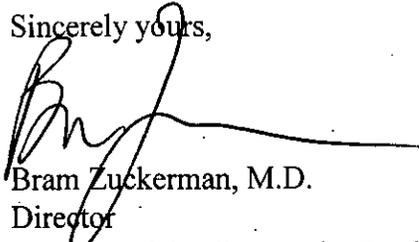
Page 2 - Mr. Albert Misajon

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

Enclosure

INDICATIONS FOR USE

AUG 13 2010

510(k) Number (if known): **K101150**

Device Name: **the PICC WAND™ Peelable Safety Introducer**

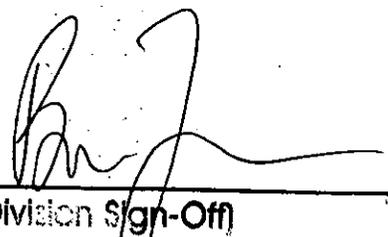
Indications for Use:

The PICC WAND™ Peelable Safety Introducer is used to facilitate the placing of an intravascular catheter through the skin into the circulatory system.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K101150