K090372

510(k) Summary

MAR 3 0 2009

5.1 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

5.2 Device Identification

A. Device Trade Name:	The WAND™ MicroAccess 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

5.3 Identification of Predicate Devices

The WAND™ MicroAccess Safety Introducer is substantially equivalent to the following devices, which are cleared for commercial distribution in the United States:

- Arrow International Emergency Infusion Device distributed under cleared 510(k) Number K840455
- BD Introsyte Precision Introducer distributed under cleared 510(k) Number K020834 (Beckton Dickinson Infusion Therapy Systems, Inc.)
- Stiffer Coaxial Micro-Introducer Set distributed under cleared 510(k) Number K071574 (Enpath Medical, Inc.)

5.4 Device Description

The WAND™ MicroAccess Safety Introducer is an integrated sterile, single-use intravascular catheter introducer. It is designed to incorporate a combination of devices into an all-in-one device that provides the clinician with a safe and simple approach to the Modified Seldinger technique, and thereby accelerate the procedure required to place in-dwelling intravascular catheters. The device includes an Introducer Needle, Guidewire, Dilator, and Introducer Sheath in a single integrated device, and incorporates a safety mechanism to guard against accidental needlestick.

5.5 Indications for Use

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

5.6 Biocompatibility and Performance Testing

A program of design verification testing including biocompatibility testing and *in vitro* bench testing has been completed to demonstrate the biological safety and biomechanical performance characteristics of the WAND™ MicroAccess Safety Introducer. Test results indicate that the device is equivalent to the predicate devices and satisfies mechanical performance requirements for its intended use. Refer to the original 510(k) application for the WAND (K081697) for information on device performance evaluation.

5.7 Sterility

The WAND™ MicroAccess Safety Introducer is provided "STERILE" by ethylene oxide gas to a sterility assurance level of 10^{-6}.

5.8 Conclusions Drawn from Studies

The results of testing demonstrate that the WAND™ MicroAccess Safety Introducer is substantially equivalent to the predicate devices in design, function, and indications for use. Refer to the original 510(k) application for the WAND (K081697) for the details of the testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2009

Access Scientific, Inc.
c/o Mr. Albert Misajon
VP, Regulatory Affairs Quality Assurance
12526 High Bluff Drive, Suite 360
San Diego, CA 92130

Re: K090372
Trade/Device Name: The WAND MicroAccess safety Introducer
Common Name: Introducer, Catheter
Regulation Number: 21 CFR 870.1340
Regulatory Class: II
Product Code: DYB
Dated: February 13, 2009
Received: February 13, 2009

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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 K090372

Device Name: The WAND™ MicroAccess Safety Introducer

Indications for Use: The WAND™ MicroAccess 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 _____
(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)

Donna R Bahnson
(Division Sign-Off)
Division of Cardiovascular Devi...

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