K042036

AUG 2 3 2004

AirGuard™ Valved Introducer
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a).

General Information:

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700 ext. 5525
Fax Number:	(801) 595-5425
Contact Person:	Glenn Norton
Date of Preparation:	August 20, 2004

Device Information:

Device Name:	**AirGuard™ Valved Introducer**
Trade Name:	**AirGuard™**
Common/Usual Name:	Catheter Introducer
Classification Name:	**74DYB** – Introducer, Catheter 21 CFR 870.1340 – Class II
Classification Panel:	Cardiovascular and Respiratory Devices

Predicate Device:

MedAmicus FlowGuard™Peelable Introducer, 510(k) K040150, FDA clearance date 02/18/2004

Summary of Change:

The modification to the MedAmicus FlowGuard™Peelable Introducer is a passive valve design for improved reduction of air and blood leakage during percutaneous catheter placement.

Device Description:

AirGuard™ Valved Introducers have a PTFE sheath and are available in 15Fr and 16.5Fr sizes, and in lengths of 13cm and 18cm.

Intended Use of Devices:

AirGuard is recommended for use in the percutaneous insertion of catheters in the venous system.

Technological Comparison to Predicate Devices:

The technological characteristics of the AirGuard Valved Introducer are substantially equivalent to those of the predicate FlowGuard Peelable Introducer in terms of intended use, application, user population, basic design, performance, labeling, packaging, and sterilization method. Bench performance test results met all requirements and were comparable to the predicate device.

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Non-Clinical Performance Data

Design verification testing was conducted in conformance to in-house protocols, and performed or evaluated based on the following standards:

- *AAMI/ANSI/ISO-10993-1: 1997, Biological evaluation of medical devices – Part 1: Evaluation and testing, and the FDA Modified ISO 10993 Test Profile*
- *AAMI/ANSI/ISO 11135*:1994, *Medical devices – Validation and routine control of ethylene oxide sterilization*
- *ISO 11070:1998(E), Sterile single-use intravascular catheter introducers*

Results from biocompatibility testing met the requirements of ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and the FDA Modified ISO 10993 Test Profile for externally communicating, direct blood-contacting, limited-exposure devices.

All test results confirm the subject device to be substantially equivalent to the predicate device.

Conclusion

AirGuard Valved Introducers met all performance criteria of design verification as specified by applicable standards, test protocols and/or customer inputs. Based on FDA's decision trees, the AirGuard Valved Introducer is substantially equivalent to the legally marketed predicate device, the MedAmicus FlowGuard™ Peelable Introducer, 510(k)# K040150, clearance date 02/18/2004.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2004

Bard Access Systems, Inc. (BAS)
c/o Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K042036
Trade/Device Name: AirGuard™ Valved Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: July 27, 2004
Received: July 29, 2004

Dear Mr. Mosenkis:

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 the . . 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 Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

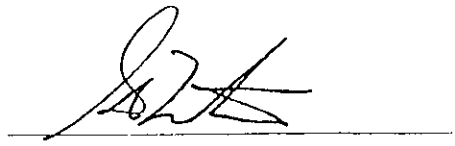
Section 1-B

AirGuard™ Valved Introducer
510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Specialist of Bard Access Systems, that this notification [510(k)] for the AirGuard™ Valved Introducer is indicated for the following:

*"The **AirGuard™** Valved Introducer is indicated for use in the percutaneous insertion of catheters in the venous system."*

Signature of 510(k) Submitter: 

Printed Name of Submitter: Glenn Norton

Date: 7-7-04

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

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

510(k) Number K042056

Division Sign-Off
Office of Device Evaluation