K071095

Section 5
510(k) Summary
21 CFR 807.92(a)

MAY 18 2007

5.1 General Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Wholly owned Subsidiary of C. R. Bard, Inc.]
Address:	5425 West Amelia Earhart Drive Salt Lake City, Utah 84116
Telephone Number:	(801) 595-0700 ext. 7175
Fax Number:	(801) 595-5425
Contact Person:	JiHyun Kim
Date of Preparation:	January 31, 2007
Registration Number:	1720496
Additional Registration Numbers:	
C. R. Bard:	2212754

5.2 Subject Device Information

Device Name:	**Aspira™ Pleural Drainage System**
Trade Name:	**Aspira™**
Common/Usual Name:	Patient Care Suction Apparatus
Classification Name:	Patient Care Suction Apparatus 21 CFR 870.5050, Class II 74 DWM – Patient Care Suction Apparatus
Classification Panel:	Cardiovascular devices

5.3 Predicate Device Information

Device Name:	**Denver® PLEURX®** Pleural Catheter Kit and **Denver® PLEURX®** Home Drainage Kit
Trade Name:	**Denver® PLEURX®**
Common/Usual Name:	Patient Care Suction Apparatus
Classification Name:	Patient Care Suction Apparatus 21 CFR 870.5050 – Class II 74 DWM –Patient Care Suction Apparatus
Classification Panel:	Cardiovascular devices
510(k) Clearance:	K971753, concurrence date June 27, 1997. K010642, concurrence date March 20, 2001 K011831, concurrence date June 28, 2001 K051084, concurrence date June 13, 2005 K052436, concurrence date October 6, 2005

5.4 Intended Use

The **Aspira™** Pleural Drainage System is intended for long-term intermittent drainage of pleural fluid accumulated in the pleural cavity for the purpose of relieving symptoms associated with pleural effusion.

5.5 Indications for Use

The **Aspira™** Pleural Drainage System is indicated for intermittent drainage of recurrent and symptomatic pleural effusions. The catheter is intended for long-term access to the pleural cavity in order to relieve symptoms such as dyspnea and chest discomfort associated with malignant pleural effusion and other recurrent effusions.

The **Aspira™** Drainage Bag is indicated for use only with the **Aspira™** Drainage Catheter for intermittent drainage.

The **Aspira™** Dressing Kit is indicated for dressing of a catheter and exit site.

The **Aspira™** Luer Adapter is intended to provide access to the **Aspira™** Drainage Catheter. It is used to drain fluid using standard wall suction, syringe or other appropriate method.

The **Aspira™** Valve Assembly attaches to the **Aspira™** Drainage Catheter. The **Aspira™** Repair Kit is for the repair of the **Aspira™** Drainage Catheter and replacement of the **Aspira™** Valve.

5.6 Device Description

The **Aspira™** Pleural Drainage System is designed for long-term intermittent drainage of recurrent and symptomatic pleural effusions. The primary components of the system are the **Aspira™** Pleural Drainage Catheter and the **Aspira™** Drainage Bag.

The **Aspira™** Pleural Drainage Catheter is a long-term indwelling silicone catheter used to drain accumulated fluid from the pleural cavity to relieve symptoms associated with pleural effusion. The fenestrated catheter is implanted in the patient's chest cavity enabling the patient or caregiver to perform intermittent drainage of their pleural effusion at home.

The **Aspira™** Drainage Bag is used to collect pleural fluid by gravity. The drainage bag attaches to the implanted catheter and is activated using an in-line silicone pump.

The **Aspira™** Luer Adapter is designed to access the **Aspira™** Drainage Catheter. The luer adapter is connected to wall suction or a syringe to perform intermittent drainage or catheter maintenance.

The **Aspira™** Valve assembly attaches to the proximal end of the **Aspira™** Pleural Drainage Catheter to prevent fluid or air exchange through the catheter when not in use.

The **Aspira™** Pleural Drainage System provides patients with a convenient method to relieve pleural effusion symptoms at home.

5.7 Technological Comparison to Predicate Device

The technological characteristics of the **Aspira™** Pleural Drainage System is substantially equivalent to the predicate device, **Denver® PLEURX®** Pleural Catheter Kit and Home Drainage Kit, in terms of intended use, application, user population, basic design, performance and labeling.

5.8 510(k) Substantial Equivalence Decision Tree

New device is compared to Marketed Device?

- Yes. **Aspira™** Pleural Drainage System was compared to the legally marketed predicate device, **Denver® PLEURX®.**

Does the new device have the same indication statement and intended use as the predicate?

- Yes. The Indications for Use and the intended use are the same as that of the predicate with minor verbiage changes.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)?

- No. The differences do not alter the intended use of the device.

Does the new device have the same technological characteristics (e.g. design, materials, etc.)?

- Not in all regards. The principles of operation and basic design are the same as the predicate device. The main differences of the **Aspira™** Pleural Drainage system from the **Denver® PLEURX®** are a pump chamber initiating pleural fluid flow and a drainage bag collecting pleural fluid drained by gravity.

Could the new characteristics affect safety or effectiveness?

- Yes. The design changes may affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety or effectiveness questions?

- No. Safety and effectiveness questions are the same as for the predicate device.

Do accepted scientific methods exist for assessing effects of the new characteristics?

- Yes. The device performance was evaluated based on the following standards.

BS EN 1617	Sterile drainage catheters and accessory devices for single use
BS EN 1618	Catheters Other Than Intravascular Catheters - Test Methods for Common Properties
BS EN ISO 14630	Non-Active Surgical Implants – General Requirements
ISO 10993-1	Biological Evaluation of Medical Devices Part 1: Evaluation and Testing
ISO 10993-7	Biological Evaluation of Medical Devices Part 7: Ethylene Oxide Sterilization Residuals
ASTM F 640-79	Standard Test methods for Radiopacity of Plastics for Medical Use

ISO 594-1	Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements
ISO 594-2	Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock Fittings
ISO 8669-2	Urine Collection Bags Part 2
AAMI ISO 14538	Biological Evaluation of Medical Devices - Establishment of Permissible Limits for Sterilization and process Residues Using Health -Based Risk Assessment
BS EN 550	Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
ISO 11135	Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
ISO 11737-1	Sterilization of Medical Devices – Microbiological Methods – Part 1: Estimation of Population of Microorganisms on Products
ISO 14971-1	Medical Devices – Risk Management – Part 1: Application of Risk Analysis

Are performance data available to assess effects of new characteristics?

- Yes. Verification testing was performed according to the protocols developed based on the standards listed above.

Performance data demonstrate equivalence?

- Yes. The **Aspira™** Pleural Drainage System met performance criteria of the safety and effectiveness tests performed and, based on FDA's decision tree, is substantially equivalent to the predicate device **Denver® PLEURX** Pleural Catheter Kit and Home Drainage Kit covered by K971753, K010642, K011831, K051084, K052436.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2007

Bard Access Systems, Incorporated
C/O Mr. Bradley J. Bonnette
Responsible Third Party Official
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K071095
Trade/Device Name: Aspira™ Pleural Drainage System
Regulation Number: 870.5050
Regulation Name: Patient Care Suction Appartus
Regulatory Class: II
Product Code: DWM
Dated: April 17, 2007
Received: April 18, 2007

Dear Mr. Bonnette:

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 Office of Compliance at (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use

510(k) Number (if known): _____

Device Name: **Aspira™** Pleural Drainage System

Indications for Use:

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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