

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

JUL 18 2008

5.1 General Information

Submitter Name: **Bard Access Systems, Inc. (BAS)**
[Wholly owned Subsidiary of C. R. Bard, Inc.]
Address: 605 North 5600 West
Salt Lake City, Utah 84116
Telephone Number: (801) 595-0700 ext. 5428
Fax Number: (801) 595-5425
Contact Person: Henry Boland
Date of Preparation: May 6, 2008
Registration Numbers:
Bard Access Systems: 3006260740
C. R. Bard: 2212754

5.2 Subject Device Information

Device Name: **Aspira* Peritoneal Drainage System**
Trade Name: **Aspira***
Common/Usual Name: Catheter, peritoneal, long-term indwelling
Classification Name: Peritoneal dialysis system and accessories
21 CFR 876.5630, Class II
FJS - Peritoneal dialysis system and accessories
Classification Panel: Gastroenterology/Urology

5.3 Predicate Device Information

Device Name: **Cardinal Health (formerly Denver Biomedical)**
PLEURX™ Peritoneal Catheter Kit and PLEURX™
Drainage Kit
Trade Name: **PLEURX™**
Common/Usual Name: Catheter, peritoneal, long-term indwelling
Classification Name: Peritoneal dialysis system and accessories
21 CFR 876.5630 – Class II
FJS - Peritoneal dialysis system and accessories
Classification Panel: Gastroenterology/Urology
510(k) Clearance: K051711, concurrence date November 15, 2005

5.4 Intended Use

The **Aspira*** Peritoneal Drainage System is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.

5.5 Indications for Use

The **Aspira*** Peritoneal Drainage System is indicated for intermittent drainage of recurrent and symptomatic malignant ascites. The catheter is intended for long-term access of the peritoneal cavity in order to relieve symptoms such as dyspnea or other symptoms associated with malignant ascites.

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, water seal drainage system, glass vacuum bottle, 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 Assembly.

5.6 Device Description

The **Aspira*** Peritoneal Drainage System is designed for long-term intermittent drainage of recurrent and symptomatic malignant ascites. The **Aspira*** Peritoneal Drainage System provides patients with a convenient method to relieve malignant ascites symptoms at home. The primary components of the system are the **Aspira*** Peritoneal Drainage Catheter and the **Aspira*** Drainage Bag.

The **Aspira*** Peritoneal Drainage Catheter is a long-term indwelling silicone catheter used to drain accumulated fluid from the peritoneal cavity to relieve symptoms associated with malignant ascites. The fenestrated catheter is placed in the patient's abdominal cavity enabling the patient or caregiver to perform intermittent drainage of their malignant ascites at home.

The **Aspira*** Drainage Bag is used to collect peritoneal fluid by gravity. The drainage bag attaches to the placed 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*** Drainage Catheter to prevent fluid or air exchange through the catheter when not in use.

5.7 Technological Comparison to Predicate Device

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

* Bard and Aspira are trademarks and/or registered trademarks of C. R. Bard, Inc. or an affiliate.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2008

Mr. Henry Boland
Associate R.A. Specialist
Bard Access Systems, Inc.
605 North 5600 West
SALT LAKE CITY UT 84116

Re: K081288
Trade/Device Name: **Aspira*** Peritoneal Drainage System
Regulation Number: 21 CFR §876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: FJS
Dated: July 1, 2008
Received: July 2, 2008

Dear Mr. Boland:

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.

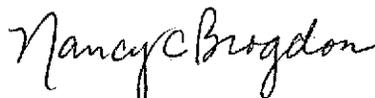
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

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 Biometric's (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,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K081288

Bard Aspira* Peritoneal Drainage System
Traditional 510(k)

1081

Section 4
Indications for Use

510(k) Number (if known): K081288

Device Name: Aspira* Peritoneal Drainage System

Indications for Use:

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*Aspira is a trademark and/or registered trademark of C. R. Bard, Inc. or an affiliate.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K081288