K070879

Bard Urological Division
C. R. Bard, Inc.
13183 Harland Dr.
Covington, GA 30014

APR 24 2007

BARD

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Address:	13183 Harland Dr. Covington, Georgia 30014
Contact Person:	John Knorpp
Contact Person's Phone:	(678) 342-4920
Contact Person's Fax:	(770) 788-5513

B. Device Name:

Trade Name(s):	Bard malecot and pezzer drains
Common/Usual Name:	Malecot and pezzer drains
Classification Names:	78 FEW – (Catheter, Malecot)
CFR Reference:	21 CFR 876.5090

C. Predicate Device Name:

Trade Name(s):	Bard malecot and pezzer drains (K910197 and K910846)

D. Device Description:

The drains are composed of a straight or angled, single lumen catheter shaft. The proximal end, which remains external to the patient, is a funnel for connection to a urine collection device. The funnel is printed with a product code, date code, product type and French size. The distal end, which is placed in the patient, is offered in various configurations including whistle tip, 2-wing, 4-wing, retention head with drainage eyes or open end retention head. The entire drain is composed of natural rubber latex.

E. Intended Use:

Bard malecot and pezzer drains are intended for use in the drainage of urine. The drains are inserted suprapubically into the bladder or through a nephrostomy tract.

F. Technological Characteristics Summary:

The modified device has the same intended use, general design and fundamental scientific technology as the predicate device.

G. Performance Data Summary:

The Bard malecot and pezzer drains referenced in this submission are held to the same design, manufacture, and performance specifications as those catheters currently manufactured by Bard. The appropriate design verification and validation activities for the modifications to the device were conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 24 2007

John C. Knorpp, RAC
Manager, Regulatory Affairs
Bard Urological Division
C. R. Bard, Inc.
13183 Harland Drive
COVINGTON GA 30014

Re: K070879
Trade/Device Name: Bard Malecot and Pezzer Drains
Regulation Number: 21 CFR §876.5090
Regulation Name: Suprapubic urological catheter and accessories
Regulatory Class: II
Product Code: FEW
Dated: March 27, 2007
Received: March 30, 2007

Dear Mr. Knorpp:

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 (Premarket Approval), 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 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" (21 CFR 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,

Nancy C. Brogdon

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

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K070879

Device Name: Bard Malecot and Pezzer Drains

Indications for Use:

Bard malecot and pezzer drains are intended for use in the drainage of urine. The drains are inserted suprapubically into the bladder or through a nephrostomy tract.

Prescription Use X ~~AND~~/OR Over-The-Counter Use _____
(Part 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070879

(Recommended Format 11/13/2003)