

K050875

Bard Urological Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

MAY 26 2005



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 INFORMATION:

Submitter's Name:	C. R. Bard, Inc.
Address:	Bard Urological Division 8195 Industrial Blvd. Covington, GA 30014
Contact Person:	John C. Knorpp
Contact Person's Telephone Number:	770-784-6451
Contact Person's Fax:	770-784-6419
Date of Preparation:	April 5, 2005

B. DEVICE NAME:

Trade Name(s):	Bard® U-Balloon Dilation Catheter
Common/Usual Name:	Balloon Dilation Catheter
Classification Names:	78 EZN – Dilator, Catheter, Ureteral
CFR Reference:	21 CFR 876.5470

C. PREDICATE DEVICE NAME:

Trade Names: Bard® UroForce™ Balloon Dilation Catheter

D. DEVICE DESCRIPTION:

The Bard® U-Balloon Dilation Catheter is composed of a dual lumen shaft with inflation and guidewire lumens and a dilation balloon on the distal end. The catheter has two radiopaque bands which define the balloon working length and facilitate radiographic visualization and placement. A high pressure stopcock is attached to the inflation lumen.

E. INTENDED USE:

The Bard® U-Balloon Dilation Catheter is used for dilation of the urinary tract.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The subject Bard® U-Balloon Dilation Catheter has the same intended use, general design and fundamental scientific technology as the predicate device.

G. PERFORMANCE DATA SUMMARY:

The appropriate testing to determine substantial equivalence was completed in accordance with *Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilation Catheters* (January 24, 1992).



MAY 26 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John C. Knorpp
Manager, Regulatory Projects
Bard Urological Division
C. R. Bard, Inc.
8195 Industrial Blvd.
COVINGTON GA 30014-2655

Re: K050875
Trade/Device Name: Bard U-Balloon Dilation Catheter
Regulation Number: 21 CFR §876.5470
Regulation Name: Ureteral dilator
Regulatory Class: II
Product Code: EZN
Dated: April 5, 2005
Received: April 6, 2005

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.

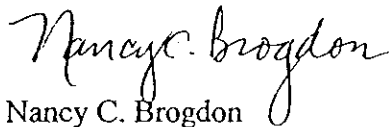
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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/dsma/dsmamain.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

1.3 Indications for Use Statement

510(k) Number (if known): K050875

Device Name: Bard® U-Balloon Dilation Catheter

Indications for Use:

The Bard® U-Balloon Dilation Catheter is indicated for dilation of the urinary tract.

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)

David L. Byrnes
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050875

(Recommended Format 11/13/2003)