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

JAN 31 2000

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BARD

SECTION VI

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Address:	8195 Industrial Blvd., Covington, GA 30014
Contact Person:	Angela L. Bunn
Contact Person's Phone:	770-784-6135
Contact Person's Fax:	770-784-6419
Date of Preparation:	November 10, 1999

B. Device Name:

Trade Name:	Bard® UroForce™ Balloon Dilation Catheter
Common/Usual Name:	Balloon Dilation Catheter
Classification Name:	Dilator, Catheter, Ureteral

C. Predicate Device Name(s):

Trade Name:	Opti-Plast® Centurion™ 5.5F PTA Catheter
Trade Name:	Bard® A-Trac Urological Balloon Dilation Catheter

D. Device Description:

The Bard UroForce Balloon Dilation Catheter is a dual-lumen catheter with a Nydex® two-layer nylon balloon mounted on its distal tip and with two radiopaque markers beneath the balloon that define the working length. The lumen labeled "balloon" is for balloon inflation. The additional lumen allows the catheter to track over a 0.038"(.97mm) guidewire and can be used for monitoring of pressure or infusion of medication and/or contrast medium.

E. Intended Use:

The Bard UroForce Balloon Dilation Catheter is indicated for dilation of the urinary tract.

F. Technological Characteristics Summary:

Table VI-1 provides a comparison summary of the technological characteristics of the Bard UroForce Balloon Dilation Catheter versus the predicate devices.

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Table VI-1

Summary of Equivalence of the
Bard® UroForce™ Balloon Dilation Catheter to Predicate Devices

Characteristics	UroForce Balloon Dilation Catheter	Opti-Plast Centurion PTA Catheter	A-Trac Urological Catheter
Indications For Use	The Bard UroForce Balloon Dilation Catheter is indicated for dilation of the urinary tract.	The Opti-Plast Centurion 5.5F PTA Catheter is recommended for use in the Percutaneous Transluminal Angioplasty (PTA) of the Iliac, Femoral and Renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The catheter is not for use in the Coronary arteries.	The Bard A-Trac Urological Balloon Dilation Catheter is indicated for use in the dilation of the ureter or urethra through the working channel of an endoscope.
Reuse Status	Disposable. For single patient use only.	Disposable. For single patient use only.	Disposable. For single patient use only.
Sterile	Yes	Yes	Yes
Catheter Balloon Material	Nylon, 2 layers	Nylon, 2 layers	PET, Single layer
X-Ray Opaque	yes	yes	yes
Fr. Size	6	5.5	5
Balloon Lengths	4, 6, 10 cm	2, 4 cm	4, 8, 10 cm
Balloon Diameters	4, 5, 6, 7, 8 mm	4, 5, 6, 7, 8, 9, 10 mm	4, 5, 6, 7, 8 mm
Operating Pressure	10 atm	10 atm	10 atm
Rated Burst Pressures	25 atm (max.)	17-20 atm	12-15 atm
Overall Catheter Length	89.5 cm	86 cm**	96 cm
Guidewire Lumen Length	85.5 cm	84.5 cm**	95.5 cm
Active Shaft Length	75 cm*	75 cm**	75 cm*
Guidewire Compatibility	0.038"	0.035"	0.035"
Shaft/Tip Design (under balloon)	one piece with drawn down tip	two piece with bonded tip	two piece with bonded tip
Stopcock Attached	Yes	No	No
Stylet	Yes	Yes	Yes
Balloon Sheath	Yes	Yes	Yes

* Excludes strain relief

** Shorter and longer shaft lengths are available

G. Performance Data:

Performance and functional testing standards are based on the FDA "Draft Guidance for the Content of Premarket Notifications for Urological Balloon Dilatation Catheters," dated January 24, 1992. Bench testing was conducted for the following characteristics: balloon burst strength, balloon distensibility, balloon inflation/deflation time and balloon diameter and profile. The test results indicate that the Bard UroForce Balloon Dilation Catheter is substantially equivalent to the stated predicate device, that there are no new safety or effectiveness issues, and that the device can be utilized for its stated indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2000

Ms. Angela L. Bunn
Regulatory Affairs Associate
C. R. Bard, Inc.
8195 Industrial Boulevard
Covington, GA 30014

Re: K993840
Bard® UroForce™ Balloon Dilation Catheter
Dated: November 10, 1999
Received: November 12, 1999
Regulatory Class: II
21 CFR §876.5470/Procode: 78 EZN

Dear Ms. Bunn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION I - D

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K993840

Device Name: Bard® UroForce™ Balloon Dilation Catheter

Indications for Use:

The Bard® UroForce™ Balloon Dilation Catheter is indicated for dilation of the urinary tract.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1/2/96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993840