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K032521
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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 INFORMATION:

Submitter's Name:	C. R. Bard, Inc., Urological Division
Address:	8195 Industrial Blvd. Covington, GA 30014
Contact Person:	Frances E. Harrison, RAC
Contact Person's Telephone Number:	770-784-6257
Contact Person's Fax:	770-784-6419
Date of Preparation:	August 7, 2003

B. DEVICE NAME:

Trade Name:	Bard® Dual Lumen Ureteral Catheter
Common / Usual Name:	Ureteral Catheter
Classification Name:	Ureteral Catheter (21 CFR 876.5130)

C. PREDICATE DEVICE NAME:

Trade Name: Bard® Dual Lumen Ureteral Catheter

D. DEVICE DESCRIPTION:

The Dual Lumen Ureteral Catheter is a bifurcated catheter with one lumen used for the passage of a guidewire and the other lumen used to inject or drain fluids. Each "Y" extension employs a female luer lock fitting used for connection to a syringe. The Dual Lumen is available in 10 Fr. with the catheter tip tapered to approximately 6 Fr. The working length of the catheter is 50 cm.

E. INTENDED USE:

The Bard® Dual Lumen Ureteral Catheter is intended to facilitate drainage and retrograde pyelogram of the upper urinary tract. This catheter will allow access to and navigation of a torturous ureter using standard endoscopic techniques.

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY:

The Bard® Dual Lumen Ureteral Catheter is constructed of polyurethane. It has the same intended use, general design and is manufactured from the same biocompatible materials as the predicate devices.

G. PERFORMANCE DATA SUMMARY:

The Bard® Dual Lumen Ureteral Catheter is constructed with biocompatible materials and has been tested for performance and found equivalent to the predicate device.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Frances E. Harrison, RAC
Director, Regulatory Affairs
C.R.Bard, Incorporated
8195 Industrial Boulevard
COVINGTON GA 30014Re: K032521
Trade/Device Name: Bard® Dual Lumen
Ureteral Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and
accessories
Regulatory Class: II
Product Code: 78 EYB
Dated: August 7, 2003
Received: August 18, 2003

Dear Ms. Harrison

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 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.

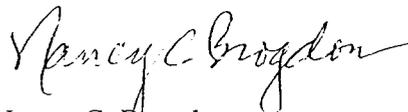
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

K032521

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032521

Device Name: Bard® Dual Lumen Ureteral Catheter

Indications for Use:

The Bard® Dual Lumen Ureteral Catheter is intended to facilitate drainage and retrograde pyelogram of the upper urinary tract. This catheter will allow access to and navigation of a torturous ureter using standard endoscopic techniques.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use (Per 21 CFR 801.109)

OR Over-The-Counter Use

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032521

(Optional Format 1/2/96)