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

K030438

MAR 1 7 2003

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:	8195 Industrial Blvd. Covington, Georgia 30014
Contact Person:	Frances E. Harrison, RAC
Contact Person's Phone:	(770) 784-6257
Contact Person's Fax:	(770) 784-6419
Date of Preparation:	November 13, 2002

B. Device Name:

Trade Name:	Bard® AquaGuide™ Ureteral Conduit
Common / Usual Name:	Ureteral Conduit
Classification Name:	Endoscope and Accessories

C. Predicate Device Name: Applied Medical Ureteral Access Sheath Set

Trade Name: Same as above

D. Device Description: The Bard® AquaGuide™ Ureteral Conduit is a two-component ureteral dilation system which contains multiple lumens for injection and aspiration of fluids as well as passage of endoscopes and related instruments. The system consists of a hydrophilic-coated introducer with female luer connector and a hydrophilic-coated dual-lumen sheath with multi-function access hub. The system is available in three lengths: 25, 35 and 55cm and with either a 10Fr. Introducer with 12-14 Fr. sheath or a 12 Fr. Introducer with 14-16 Fr. sheath.

E. Intended Use: The Bard® AquaGuide™ Ureteral Conduit is indicated for use in endoscopic urology procedures where ureteral dilation and continued ureteral access is desired for injection and aspiration of fluids and insertion and removal of endoscopes and related instruments.

F. Technological Characteristics Summary: The Bard® AquaGuide™ Ureteral Conduit has a lubricious hydrophilic coating and is constructed of materials that soften at body temperature to enhance patient comfort. The device can be placed over a 0.038" guidewire, allows for passage of endoscopes and related instruments, allows for injection and aspiration of fluids and provides for continuous flow.

G. Performance Data Summary: The Bard® AquaGuide™ Ureteral Conduit is constructed of biocompatible materials. The additional lumen reduces the potential for hypervolemia (excess fluid build-up). The following table is a summary of the technical features of the Bard® AquaGuide™ Ureteral Conduit compared to the predicate device.

Product Feature	Bard AquaVue Ureteral Sheath (Subject Device)	Applied Medical Ureteral Access Sheath Set (Predicate Device)
Size Ranges	10Fr Introducer 12014Fr Sheath 25,35,55cm Lengths	10Fr Dilator 12-16Fr Sheath 35,55cm Lengths
	12Fr Introducer 14-16Fr Sheath 25,35,55cm Lengths	12Fr Introducer 14-18Fr Sheath 20,28,35,55cm Lengths 14Fr Introducer 14-18Fr Sheath 20,28,35cm Lengths
Material	Polyurethane	Polyurethane w/Internal SS Coil
Softening Material?	Yes	Yes
Radiopaque?	Yes	Yes
Hydrophilic Coating?	Yes	Yes
Irrigation/Aspiration ?	Yes, Introducer & Sheath Side Lumen	Yes, Introducer Only
Dual-Lumen Sheath?	Yes	No
Locking Mechanism?	Yes	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2003

C. R. Bard
c/o Mr. Robert Mosenkis
President, CITECH
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K030438
Trade/Device Name: Bard® AquaGuide™ Ureteral Conduit, Models 131125, 131135, and 131155 (with 10 Fr. Introducer, 12-14 Fr. Sheath and lengths of 25, 35 or 55cm); and Models 131225, 131235, and 131255 (with 12 Fr. Introducer, 14-16 Fr. Sheath and lengths of 25, 35 or 55cm)
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Code: II
Product Code: 78 FED
Dated: March 4, 2003
Received: March 5, 2003

Dear Mr. Mosenkis:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030438

Device Name: Bard® AquaGuide™ Ureteral Conduit

Indications for Use:

The Bard® AquaGuide™ Ureteral Conduit is indicated for use in endoscopic urology procedures where ureteral dilation and continued ureteral access is desired for injection and aspiration of fluids and insertion and removal of endoscopes and related instruments.

(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,
and Radiological Devices
510(k) Number K030438