K983101

C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30209

NOV 3 1998

BARD

SECTION VI

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:	Georgia C. Abernathy
Contact Person's Phone:	(770) 784-6454
Contact Person's Fax:	(770) 784-6419
Date of Preparation:	8-31-98

B. Device Name:

Trade Name:	Bardex I. C. 4-Way Foley Catheter
Common / Usual Name:	Antimicrobial Catheter
Classification Name:	Catheter, Urological (Antimicrobial) and Accessories

C. Predicate Device Names:

Trade Name:	Bard Latex Urinary Catheters
Trade Name:	Bard Hydrogel/Silver-Coated Foley Catheter

D. Device Description:

The Bardex I. C. 4-Way Foley Catheter is a new catheter design incorporating the addition of a fourth lumen for prostatic drainage and the addition of several prostatic drainage eyes proximal to the balloon.

E. Intended Use:

The Bardex I. C. 4-Way Foley Catheter is indicated for use in bladder/urinary tract drainage/irrigation and to assist in hemostasis and surgical site drainage following procedures such as transurethral resection of the prostate.

F. Technological Characteristics Summary:

Table VI-1 provides a tabulated comparison summary of the technological characteristics of the Bardex I. C. 4-Way Foley Catheter versus the predicate device.

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Table VI-1
Comparison Summary of Technological Characteristics

Product Characteristic	Bard 4-Way Catheter (this 510(k))	Bard Latex Urinary Catheters (Predicate device) (#K922431)	Bard Hydrogel/Silver-Coated Foley Catheter (Predicate device) (#K910318)
Indications or Intended Use	The Bardex I.C. 4-Way Foley Catheter is indicated for use in bladder/urinary tract drainage/irrigation and to assist in hemostasis and surgical site drainage following procedures such as transurethral resection of the prostate.*	Bard Catheters are intended for use in the drainage and/or collection and/or measurement of urine and in bladder/urinary tract irrigation and to assist in hemostasis following surgery such as transurethral resection of the prostate.	The Bard Hydrogel/Silver-Coated Foley Catheter is intended for use in the drainage and/or collection and/or measurement of urine and in bladder/urinary tract irrigation and to assist in hemostasis following surgery such as transurethral resection of the prostate.
Disposable	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Catheter Base Material	Red Latex	Red Latex	Red Latex
X-Ray Opaque	Yes	Yes	Yes
Coating	Silver/Hydrogel	Hydrogel	Silver/Hydrogel
Drainage Eyes Proximal to Balloon	5 Drainage Eyes *	None	None
Tip Type – Drainage Eyes Distal to Balloon	Open Concave Tip (Couvelaire) and 3 additional eyes	Single Eye	Open Concave Tip (Couvelaire) and 2 opposed eyes
Fr. Sizes Available	18-24 Fr.	22-24 Fr.	18-24 Fr.
Foley Balloon Size	30cc	30cc	30cc
Available Packaged Singly	Yes	Yes	Yes
Tip Shape	Coude	Coude	Coude
Number of Lumens	4 lumens*	3 lumens	3 lumens
Catalog # of example	1865SIXX**	6003LXX**	1859SIXX**

* New feature(s) this 510(k)

** XX = French size (e.g., 1865SIXX = 1865SI18, 1865SI20, 1865SI22, 1865SI24)

G. Performance Data Summary:

The Bardex I. C. 4-Way Foley Catheter referenced in this submission is held to the same design, manufacture, and performance specifications as those catheters currently manufactured. Performance and functional testing standards are based on the "Guidance for the Content of Premarket Notifications for Conventional and Antimicrobial Foley Catheters" dated September 12, 1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 1998

Ms. Georgia Abernathy
Regulatory Affairs Associate
C.R. Bard, Incorporated
Medical Division
8195 Industrial Blvd.
Covington, Georgia 30209

Re: K983101
Bardex I.C. 4-Way Foley Catheter
Dated: October 22, 1998
Received: October 26, 1998
Regulatory Class: II
21 CFR §876.5130/Product Codes: 78 MJC

Dear Ms. Abernathy:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
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): _____

Device Name: Bardex I. C. 4-Way Foley Catheter

Indications for Use:

The Bardex I. C. 4-Way Foley Catheter is indicated for use in bladder/urinary tract drainage/irrigation and to assist in hemostasis and surgical site drainage following procedures such as transurethral resection of the prostate.

(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

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