Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30209-2695

DEC 10 1999

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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., Medical 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:	October 8, 1999

B. Device Name:

Trade Name:	Bardex® I. C. Pediatric Foley Catheter
Common / Usual Name:	Latex Pediatric Foley Catheter with lubricious and silver coating
Classification Name:	Urological catheter (antimicrobial) and accessories

C. Predicate Device Names:

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

D. Device Description:

The Bardex I. C. Pediatric Foley Catheter is a two-way latex Foley catheter with silver and hydrogel coatings.

E. Intended Use:

The Bardex I. C. Pediatric Foley Catheter is intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.

F. Technological Characteristics Summary:

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

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Table VI-1
Comparison Summary of Technological Characteristics

Comparison Characteristic	[illegible]	[illegible]	[illegible]	[illegible]	Difference
Indications or Intended Use	The Bardex I. C. Pediatric Foley Catheter is intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.	The Bard Hydrogel/ Silver-Coated Foley Catheter is intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.	Bard catheters are intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter/drain through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter/drain, such as a nephrostomy tract.	Bard Hydrogel-Coated Foley catheters are intended for use in drainage of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.	No substantial difference
Disposable	Yes	Yes	Yes	Yes	None
Sterile	Yes	Yes	Yes	Yes	None
Design					
Catheter Base Material	latex	latex	latex	latex	None
French sizes Available**	8 and 10 Fr.	12-30 Fr.	Includes 8 and 10 Fr.	Includes 8 and 10 Fr.	Pediatric sizes added to hydrogel/ silver-coated catheter line
Balloon sizes	3cc	Smallest is 5cc	Includes 3cc	Includes 3cc	#1 identical to #3 and #4
Coating					
Silver Coating Form	Metallic	Metallic	N/A	N/A	#1 and #2 identical
Lubricious Coating	Hydrogel hydrophilic polymer	Hydrogel hydrophilic polymer	Hydrogel hydrophilic polymer	Hydrogel hydrophilic polymer	None
Catheter Surface Hydrogel Coated	From bifurcation to tip, internal and external including balloon	From bifurcation to tip, internal and external including balloon	From bifurcation to tip, internal and external including balloon	From bifurcation to tip, internal and external including balloon	None
Catheter Surface Silver Coated	From bifurcation to tip, internal and external including balloon	From bifurcation to tip, internal and external including balloon	N/A	N/A	#1 and #2 identical

** New feature(s) or a change in this 510(k)

G. Performance Data Summary:

The Bardex I.C. Pediatric Foley Catheter referenced in this submission is held to the same design, manufacture, and performance specifications as those Foley catheters currently manufactured. Performance and functional testing standards are based on the FDA draft "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

DEC 10 1999

Ms. Georgia C. Abernathy
Regulatory Affairs Associate
Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

Re: K993464
Bardex® I. C. Pediatric Foley Catheter
Dated: October 8, 1999
Received: October 13, 1999
Regulatory Class: II
21 CFR 876.5130/Procode: 78 KOD and 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 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): K993464

Device Name: Bardex® I. C. Pediatric Foley Catheter

Indications for Use:

The Bardex I. C. Pediatric Foley Catheter is intended for use in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy 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 K993464