2/16/99

K984136 1 of 3

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

BARD

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter Information:

Submitter's Name: C. R. Bard, Inc., Medical Division
Submitter's Address: 8195 Industrial Blvd.,
Covington, GA 30014
Contact Person's Telephone Number: 770-784-6135
Contact Person's FAX Number 770-784-6419
Date of Preparation: November 16, 1998

B. Device Name:

Bardex® Lubri-Sil™ I.C. Foley Catheter

C. Predicate Device Name:

Bardex® All-Silicone Foley Catheter
Bardex® I.C. Foley Catheter (LATEX)

D. Device Description

The Bardex® Lubri-Sil™ I.C. Foley Catheter is a two-way all-silicone Foley catheter with silver and lubricious hydrophilic coatings.

E. Intended Use:

The Bardex® Lubri-Sil™ I.C. Foley Catheter is indicated 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.

Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery such as transurethral resection of the prostate.

F. Technological Characteristics Summary:

The Bard Lubri-Sil I. C. Foley Catheter is constructed of high grade extruded clear silicone rubber with a molded tip and funnel. It is a two-lumen catheter with a drainage lumen and an inflation lumen with two-way valve. A silver coating and then a hydrophilic polymeric coating are applied to the finished catheter. The hydrophilic coating becomes very slippery when wet. The silver coating discourages bacterial adhesion to the catheter surface. The Lubri-Sil I.C. Foley Catheter is available in even shaft sizes 12-24 Fr. with a 5cc balloon and in even shaft sizes 16-24 Fr. with a 30cc balloon.

G. Performance Data:

The Bard Lubri-Sil I. C. Foley Catheter meets the following performance requirements per testing conducted according to ASTM F 623-89, when appropriate, and/or Bard testing/acceptance criteria:

- flow rate through the drainage lumen;
- resistance of the balloon to rupture when inflated to the claimed balloon volume and held under conditions approximating the usage environment for a period of seven days;
- resistance of the inflated balloon to being distorted and pulled through the bladder outlet;
- maintenance of balloon inflation to fill volume over an extended time;
- manufacturing tolerances for catheter tip, balloon and shaft diameters;
- ability of an inflated catheter that has been submerged for seven days to deflate reliably to within 4 Fr. sizes of the labeled shaft size, as applicable, including the time for such deflation;
- coefficient of friction;
- silver elution/availability;
- shaft tensile strength and tip adherence;
- balloon burst.

Testing on aged product indicates that application of the silver and hydrophilic coatings has no adverse effect on the base material of the shaft or balloon.

Testing for bacterial adherence demonstrates that there is significantly less bacterial adherence to the Lubri-Sil I.C. Foley Catheter surface than

to an uncoated silicone catheter surface. Reduced bacterial adherence to the Lubri-Sil I.C. Foley Catheter was similar to that for the Bardex® I.C. Latex Foley Catheter. Clinical isolates used in the bacterial adherence testing included: Candida albicans, Citrobacter diversus, Enterobacter cloacae, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa and Staphylococcus saprophyticus.

The Lubri-Sil I. C. Foley Catheter passes biocompatibility testing per ISO 10993-1 (cytotoxicity, systemic toxicity, mucosal irritation, sensitization and implantation).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 1999

Ms. Donna J. Wilson
Director, Regulatory Affairs
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, Georgia 30209

Re: K984136
Bardex® Lubri-Sil™ (2-way Silicone) Foley Catheter (with silver/hydrogel) and Tray
Regulatory Class: II
21 CFR 876.5130/Product Code: 78 MJC
Dated: November 16, 1998
Received: November 18, 1998

Dear Ms. Wilson:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

In addition, we have determined that your device kit contains Povidone-Iodine which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

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 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,

for 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

510(k) Number (if known):_____

Device Name: Bardex® Lubri-Sil™ I.C. Foley Catheter

Indications For Use: The Bardex® Lubri-Sil™ I.C. Foley Catheter is indicated 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.

Some Foley catheters, especially those with larger (30cc) balloons are used to assist in hemostasis following surgery 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
510(k) Number K984136