



K971627

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## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

JAN 13 1998

**Submitter and Contact Person** Richard D. Fryar  
Rochester Medical Corporation

**Name of the Device** Classification Name: Urological catheter  
Common/Usual Name: Foley catheter  
Proprietary Name: Rochester Medical Corporation  
Silicone Antibacterial Foley Catheter

**Predicate Device**

The predicate devices for purposes of substantial equivalence are the C.R. Bard Corp. Bardex® I.C. Foley Catheter (K910318), the American Pharmascal Co. Antimicrobial Foley Catheter (K871429) and the Rochester Medical All Silicone Foley Catheter (K896053).

**Intended Use of the Device**

The Silicone Antibacterial Foley Catheter is intended for short term use to provide continuous urinary bladder drainage in adult males and females requiring catheterization for surgical procedures, monitoring urine output, management of incontinence, and voiding dysfunction. The catheter has been shown to provide a statistically significant reduction in the incidence of catheter acquired bacterial urinary tract infection during the first 5 days of catheterization. This device is not intended to be used as a treatment for active urinary tract infection.

**Device Description**

The catheter consists of a standard configuration Foley catheter with a drainage lumen that exits through two drainage eyes on the proximal end. A retention balloon is located near the proximal catheter tip. The retention balloon is filled thru a second lumen with a Luer valve that extends from a side arm on the distal end of the catheter to the balloon. The catheter is coated with nitrofurazone impregnated silicone on the outside surface and inner lumen. It is available in 12, 14, 16, 18 and 20 Fr sizes. All French sizes are provided in a 16 inch length with a 5 or 10 cc size balloon.

**Technological Characteristics**

The catheter described in the 510(k) has similar technological and performance characteristics to the predicate devices. The catheter is manufactured entirely from silicone elastomer. The predicate devices are manufactured from silicone elastomer or latex. The device is supplied in French sizes from 12 to 20 with 5 or 10 cc capacity balloons. The predicate devices are available in French sizes ranging from 8 to 30 French with 3, 5, 10 and 30 cc balloons. All of the devices are supplied sterile for single use. The C.R. Bard Corp. Bardex® I.C. Foley Catheter and American Pharmascal Co. Antimicrobial Foley Catheter provide antibacterial activity through the use of a silver or silver oxide coating or impregnation of the catheter.

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materials. The Rochester Medical Silicone Antibacterial Foley Catheter provides antibacterial activity by coating the catheter with nitrofurazone.

### Testing and Test Results

Test results indicated that the Silicone Antibacterial Foley Catheter meets the requirements of ASTM 623-89 Standard Specification for Foley Catheters. Simulated use testing shows that the elution profile of the antibacterial agent from the catheter is reproducible and the agent is released at bacteriocidal levels. There has been no evidence that the catheter materials or performance are degraded with ageing. Samples of Silicone Antibacterial Foley Catheter passed Cytotoxicity, USP Systemic Toxicity, Subchronic Toxicity, Intracutaneous Injection, Muscle Implant Study, Sensitization Study, Pyrogenicity and Hemolysis. Mutagenicity testing indicated some mutagenic changes.

### In-vitro studies

In-vitro studies have shown that nitrofurazone impregnated catheter segments have antibacterial activity against clinical isolates of uro-pathogens including *Coagulase-negative staphylococci*, *S. aureus*, *Enterococcus spp.*, *C. Minutissimum*, *E. Coli*, *Enterobacter spp.*, and *Klebsiella spp.* Gram-negative bacilli including *Serratia spp.*, *Proteus spp.*, and *Pseudomonas spp.* were not inhibited by nitrofurazone impregnated catheter segments. Nitrofurazone is not effective against yeast and fungi.

### Clinical studies

A single site randomized, double-blind, controlled clinical trial was conducted to compare the antibacterial properties of the Silicone Antibacterial Catheter (nitrofurazone impregnated) to a Conventional Silicone Catheter. During the eleven month trial, a total of 344 patients (68% men, 32% women) meeting the study evaluation criteria were enrolled (mean age = 56 years, range 18 to 91) and the incidence of catheter associated urinary tract infection (CAUTI) during catheterization was recorded.

For patients with catheters inserted for 7 days or less (91.9% of population, median = 3 days), the group receiving the Silicone Antibacterial Catheter had an approximate threefold reduction in the rate of bacterial CAUTI compared to the Conventional Silicone Catheter group (2.4% vs. 6.9% incidence). The difference in actuarial survival curves for time until the occurrence of bacterial CAUTI between the two groups was found to be statistically significant ( $p = 0.007$ , Kaplan-Meier survival, Breslow logrank statistic) for the first 5 days of use.

However, the trend in the hazard ratio over time to bacterial CAUTI between the antibacterial catheter and standard catheter was found to be statistically significantly increasing ( $P=0.03$  Wald Chi Square Statistic) for the 7 days of use, resulting in the reversal of the hazard ratio in favor of the standard catheter from the 6th day.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 13 1998

Mr. Richard D. Fryar  
Vice President of Research and Development  
Rochester Medical Corporation  
One Rochester Medical Drive  
Stewartville, Minnesota 55976

Re: K971627  
Rochester Medical Silicone Antibacterial Foley Catheter  
Dated: December 5, 1997  
Received: December 8, 1997  
Regulatory class: II  
21 CFR §876.5130/Product code: 78 MJC

Dear Mr. Fryar:

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,

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

510(k) Number (if Known): K971627

Device Name: Silicone Antibacterial Foley Catheter  
Rochester Medical Corporation

Indications for Use:

**INTENDED USE**

The Silicone Antibacterial Foley catheter is intended for short term use to provide continuous urinary bladder drainage in adult males and females requiring catheterization for surgical procedures, monitoring urine output, management of incontinence, and voiding dysfunction. The catheter has been shown to provide a statistically significant reduction in the incidence of catheter acquired bacterial urinary tract infection during the first 5 days of catheterization. This device is not intended to be used as a treatment for active urinary tract infections.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Sathya  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K971627

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use