



MAR 13 1997

**14.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Submitter and Contact Person** Mary M. Wilen  
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**Name of the Device** Classification Name: Urological catheter  
Common/Usual Name: Urethral or Intermittent catheter  
Proprietary Name: Rochester Medical Corporation Personal Catheter™

**Predicate Device**  
The predicate device for purposes of substantial equivalence is the Rochester Medical All Silicone Intermittent Catheter which received marketing approval under K943851 and Bard Urology Inc. Urethral Catheters.

**Intended Use of the Device**  
The device is intended for use for urethral or intermittent catheterization. Device sizes are supplied for pediatric and adult male and female applications

**Device Description**  
The catheter consists of a single lumen catheter with two or four drainage eyes on the proximal tip. The catheter is available in a combination of French sizes and lengths to accommodate pediatric and adult male and female applications. Available catheter lengths range from 6.4 to 15.65 inches and French sizes from 6 to 26 French.

**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, plastic, latex or red rubber. The catheter is supplied with either two or four drainage eyes. The predicate devices are available with 1, 2 or 3 drainage eyes. The device is supplied in French sizes from 6 to 26. The predicate devices are available in French sizes from 6 to 26. The device is supplied in male and female lengths. The predicate devices are supplied in male and female lengths. All of the devices are supplied sterile for single use.

**Testing and Test Results**  
Test results indicated that flow rates of the Personal Catheter meet or exceed the requirements of ASTM 623-89 Standard Specification for Foley Catheters.

Samples of Personal Catheters were required to pass MEM Cytotoxicity, Sensitization Study in the Guinea Pig (Maximization Method), Acute Intracutaneous Reactivity, Genotoxicity (Ames Mutagenicity), USP Systemic Toxicity, Muscle Implant Study (2 week), and Urinary Bladder Irritation Study testing.