

510(k) Summary**SUBMITTER:** Medical Device International, Inc.

Address: 5116 Birch Road
Minnetonka, MN 55345
Telephone: 612-938-4125

CONTACT PERSON: Greg Sachs
612-938-4125

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TRADE NAME: OPTICON™ Female Urinary Catheter for Continuous Drainage
COMMON NAME: Foley Catheter
CLASSIFICATION NAME: Urological Catheter

SUBSTANTIALLY EQUIVALENT TO:

The OPTICON™ Female Urinary Catheter for Continuous Drainage is substantially equivalent to the Bardex Silicone Foley Catheter (K760093) and the Rochester Medical Female Urethral Catheter (K941692).

DESCRIPTION of the DEVICE: The OPTICON™ Female Urinary Catheter for Continuous Drainage is a sterile, single use/disposable, flexible, tubular device that is inserted through the urethra and is used to pass urine from the urinary tract when connected to standard drainage tube adaptors, tubes and bags. The catheter is manufactured from soft biocompatible silicone and comes in only one size (18 French) and length, 10.8 cm (4.3 inches). When inserted, all that is visible outside of the body is a microvalve for balloon inflation and retainer ring. The device is to be used only with standard urinary drainage tube adaptors, tubes and bags.

INDICATIONS for USE: The OPTICON™ Female Urinary Catheter for Continuous Drainage is used to pass fluids from the urinary bladder. It must be connected to standard drainage tubes, drainage tube adaptors, tubes and bags.

CLINICAL INFORMATION and SAFETY and EFFECTIVENESS:

The OPTICON™ Female Urinary Catheter for Continuous Drainage has been tested to the ASTM Standard F623-89, "Standard Performance Specification for Foley Catheter" and was found to meet all performance requirements.