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**510(k) Summary****SUBMITTER: OPTICON™ Medical Inc.**

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**DATE SUMMARY PREPARED:** February 26, 1997

**TRADE NAME:** OPTICON™ Direct Male Urinary Catheter for Continuous  
Drainage  
**COMMON NAME:** Foley Catheter  
**CLASSIFICATION NAME:** Urological Catheter

**SUBSTANTIALLY EQUIVALENT TO:**

The OPTICON™ Direct Male Urinary Catheter for Continuous Drainage is substantially equivalent to the OPTICON™ Direct Female Urinary Catheter for Continuous Drainage (K961697).

**DESCRIPTION of the DEVICE:**

The OPTICON™ Direct Male Urinary Catheter for Continuous Drainage is a sterile, single use/disposable, flexible, tubular catheter that is inserted through the urethra to pass urine from the urinary bladder, when connected to standard drainage tubes, drainage tube adaptors, tubes and bags. The catheter is manufactured from soft biocompatible silicone. The male catheter requires an introducer for insertion. OPTICON™ Medical currently recommends the use of a commonly available introducer, (such as the Bard 0420 Wire Stylet) to aid in insertion. This introducer is not sold by OPTICON™ Medical, nor is the introducer included in the packaging for the OPTICON™ Direct Male Urinary Catheter for Continuous Drainage Catheter. The catheter is to be used only with standard urinary drainage tubes, drainage tube adaptors, tubes and bags.

**INDICATIONS for USE:**

The OPTICON™ Direct Male 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™ Direct Male 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.