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SPECTRUM MedSystems Corporation P173
UNI-GARD QUIK CATH™
510(K) Notification

SPECTRUM MedSystems Corporation

2166 Michelson Drive
Irvine, CA 92715
Telephone 714/442-8400 Fax 714/442-8410

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Submitter:

SPECTRUM MedSystems Corporation
2166 Michelson Drive
Irvine, California 92715

Contact Name: Thomas L. Hursman
Fax Number: (714) 442-8410
Phone Number: (714) 442-8400

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Name of Device: UNI-GARD QUIK CATH™
Common Name: Intermittent Urinary Catheter
Classification Name: Urological Catheter and Accessories
(21 CFR 876.5130)

The legally marketed devices to which SPECTRUM MedSystems is claiming equivalence[807.92(a)(3)] is the Bard® Touchless® Plus Unisex Intermittent Catheter and the MMG/O'Neil® Sterile Field Urinary Intermittent Catheter System.

Description of the Device [807.92(a)(4)].

The UNI-GARD QUIK CATH™ is a sterile, disposable device composed of a introducer with lubricant, drainage catheter and urine collection bag. The introducer containing the lubricant is pressed into the urethral meates until it stops. The catheter is advanced through the introducer and reservoir of lubricant while perforating the introducer tip to enter the urethra. The catheter is advanced until it reaches the bladder and urine begins to flow through the catheter into the urinary collection bag.

Intended Use of the Device [807.92(a)(5)].

The UNI-GARD QUIK CATH™ is indicated for use to drain urine from the bladder and collect the urine from the bladder in a bag. The UNI-GARD QUIK CATH™ is a unisex intermittent unitized catheter system.

Technological Characteristics of Device Versus Predicate Device [807.92(a)(6)].

The basic clinical approach to bladder drainage using the UNI-GARD QUIK CATH™ and the predicate devices is the same. The Bard and MMG products use a catheter, urinary drainage bag, KY Jelly as the lubricate on exterior of the catheter and in the cap, a insertion tip or introducer tip and removable cover guard or catheter cap to form their catheter system. The design improvements over the predicate devices have been aimed at simplifying the designs,

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extending the shelf life, improving the ergonomics of the user when introducing the urine drainage catheter into the urethra, enlarging the urine collection bag to accommodate the largest of bladder drainage and increasing the length of the catheter to allow complete discharge of the bladder.

The UNI-GARD QUIK CATH™ design is simpler by eliminating the need for a removable protective guard or cap. The protective cap on the predicate devices is filled with gel lubricant and when dropped accidentally by the user can contaminate the gel used to lubricate the introducer. The sealed catheter introducer used in the UNI-GARD QUIK CATH™ has been designed to eliminate this possibility of contamination by functioning as a lubricate reservoir, a sterile barrier and a introducer. The catheter introducer places a thin medical grade lubricant film onto the catheter as it passes through the introducer lubricant reservoir. The predicate devices are pre-lubricated with large amounts of gel material deposited on the exterior of the catheter that ends up in the urethra meatus and urethral canal. The distal tip of the SPECTRUM catheter introducer is punctured by the catheter as it advances through the sealed catheter introducer tip. The tip seal on the introducer is broken after the introducer tip positions the catheter in the urethra. The catheter penetrated the distal urethra and bypasses contact with the urethral meatus to reduce the risk of infection.

Reducing the number of parts making up a medical device improves the ergonomics and the ease-of-use. UNI-GARD QUIK CATH™ accomplishes this objective with the eliminate of the cap and bag retainer ring used in constructing the predicate devices.

Extending the shelf life of the pre-lubricated predicate device products will be accomplished by substituting Medical Grade Dow Corning Polydimethylsiloxene lubricant for the traditional KY Jelly. The KY Jelly has a basic composition of chlorhexidine gluconate, glucono delta lactone, glycerin, hydroxyethyl cellulose, methyl parabin, water and sodium hydroxide. The gel is basically a water miscible gel of hydroxyethyl cellulose and upon sitting in a Tyvek pouch over time, the water evaporates and the hydroxyethyl cellulose precipitates as a powder. KY Jelly, once a lubricant then, converts to a grit after dehydration.

The UNI-GARD QUIK CATH™ contains the Polydimethylsiloxene lubricant within the pre-lubrication and primary reservoirs of the catheter introducer. The catheter and introducer when assembled together create a reservoir which resists desiccation and provide several years of shelf-life in dry storage (Refer to Attachment 2). This is in contrast to drainage catheter assemblies, such as the present predicate devices which have utilized water-based lubricants such as KY Jelly having shelf storage lives in dry storage of less then one year.

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The UNI-GARD QUIK CATH™ will use a 1800 cc collection bag rather than an 1100 cc or 1500 cc bag as used by the predicate devices. This will eliminate the use of a second catheter system to perform the additional drainage of the largest of bladders. The catheter length has also been increased by three inches to a final length of 20 inches to allow complete drainage of the bladder.