

K 962900

SEP 16 1996

Hollister Incorporated
Hollister Self Retaining Male External Urinary Catheter

510(k) Summary

1. Submitter's Name, Address and Contact Person

Submitter

Hollister Incorporated
2000 Hollister Drive
Libertyville, IL 60048

Contact Person

Joseph S. Tokarz
Manager, Regulatory Affairs
Phone (847) 680-2849
Fax (847) 918-3860

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2. Name of Device:

Hollister Self Retaining Male External Urinary Catheter

3. Name of Predicate Device(s)

Hollister Non-Rolled Male External Urinary Catheter K#940269
Mentor Active Cath Self Adhesive Male External Urinary Catheter

4. Description of Device

The Hollister Self Retaining Male External Urinary Catheter is a condom-like device made from Natural Rubber Latex. The device features a unique inner flap that aids in the protection of the penile skin from irritation due to backwash of urine and helps to maximize wear time. The external catheter is presented on a plastic collar to enable easy application and maintain the catheter shape integrity during shipping.

5. Statement of Intended Use

The Hollister Self Retaining Male External Catheter is a urosheath type incontinence device intended to be used as an external catheter to collect urine from urinary incontinent males.

6. Statement of Technological Characteristics of the Device

Currently, there are two basic types of male external catheters in commercial distribution:

1. A two-piece catheter that relies on a strip of adhesive to be placed on the penis and the urosheath adhered to the adhesive strip. There is also a two-piece catheter that relies on a velcro strip or other material to be wrapped around the urosheath after it has been placed on the penis, and
2. A self adhesive catheter that is designed with an adhesive that has been applied to the inside of the urosheath.

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The proposed device differs from these types of external catheters in that it is not a two-piece system nor does it rely on an adhesive for securement. Instead the proposed device is retained on the penis of the wearer solely by virtue of its designed shape. The proposed device is designed to contain the portion of the penis exclusive of the glans in an elastic sheath which substantially matches the diameter of the penis in its extended position so that the penis provides its own outward force against the walls of the elastic sheath which results in the retaining of the device upon the penis.

7. Biocompatibility Assessment

Material Biocompatibility: Issues of biomaterial safety or biocompatibility have been addressed based upon the biomaterial history or in separate in-vitro or in-vivo evaluations using licensed commercial reference laboratories. Each assessment was conducted based on principles and guidelines established by various governmental and standard setting organizations among these are the following:

- EN 30993, European Commission (EC) Standard
- General Program Memorandum #G95-1, United States FDA Office of Device Evaluation
- United States Pharmacopeia (USP)

The materials used to construct the Hollister Self Retaining Male External Urinary Catheter are considered biocompatible and suitable for their intended use.

8. Conclusion

Based on the information presented above and within the body of the 510(k) premarket notification, it is concluded that the Hollister Self Retaining Male External Urinary Catheter Device is safe and effective for its intended use. The Hollister Self Retaining Male External Urinary Catheter is substantially equivalent to the predicate device(s).