



Hollister Incorporated  
2000 Hollister Drive  
Libertyville, Illinois 60048-3781

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K970443

Hollister Incorporated  
Urine Collection Pouch

**510(k) Summary**

**FEB 25 1997**

**1. Submitter's name, Address and Contact Person**

Submitter

Hollister Incorporated  
2000 Hollister Drive  
Libertyville, IL 60048

Contact Person

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Date Summary Prepared - February 3, 1997

**2. Name of Device:**

Hollister Urine Collection Pouch

**3. Name of Predicate Device(s)**

Hollister Female Urine Collection Pouch, K862934

**4. Description of Device**

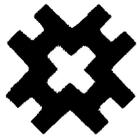
The Hollister Urine Collection Pouch is a one-piece disposable system which collects urine by encompassing the penis. The pouch is made from odor-barrier film and features a synthetic skin barrier adhesive which aids in the protection of the skin. If required the pre-cut opening in the barrier may be enlarged to accommodate the anatomy of the user. Strips of adhesive microporous tape may be used for additional security.

**5. Statement of Intended Use**

The Hollister Urine Collection Pouch is intended to collect urine from incontinent men by encompassing the penis

**6. Statement of Technological Characteristics of the Device**

The proposed device is substantially equivalent to the predicate device. The following is a chart comparing the two devices.



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**Comparison of the Proposed Urine Collection Pouch and the Predicate Device**

Characteristic	Hollister Urine Collection Pouch	Hollister Female Urinary Pouch
Premarket Notification	Current Submission	K862934
Intended Use	to collect urine from incontinent men	to collect urine from incontinent women
Barrier Adhesive	Hydrocolloid Synthetic Skin Barrier	Hydrocolloid Synthetic Skin Barrier
Barrier Backing	Non-woven Polyethylene Fabric	Closed-Cell Ethylene Copolymer Foam
Barrier Thickness	.045 inch nominal	.064 inch nominal
Pouch Film	Polyethylene/Vinylidene Chloride, Vinyl Chloride Copolymer/ Polyethylene Laminate Odor Barrier Film	Polyethylene/Vinylidene Chloride, Vinyl Chloride Copolymer/ Polyethylene Laminate Odor Barrier Film
Drain Valve	Molded Polyethylene Resin	Molded Polyethylene Resin
Drain Valve Tubing	Molded Polyvinylchloride Resin	Molded Polyvinylchloride Resin

**8. Biocompatibility**

The biocompatibility of the Urine Collection Pouch as a nonsterilized configuration was assessed based on principles and guidelines established by various governmental and standard setting organizations, such as:

- ISO 10993, International Standards Organization (ISO) Standard
- General Program Memorandum #G95-1, United States FDA Office of Device Evaluation
- United States Pharmacopeia (USP)

Material biocompatibility issues have been addressed based upon biomaterial history or in separate in vitro or in vivo laboratory evaluations using licensed commercial reference laboratories. Specific test methodology has been chosen, where appropriate, from test protocols established or recommended by the aforementioned agencies or organizations. Product use conditions have been mimicked in testing procedures where possible. These evaluations have been contracted either by Hollister or the suppliers of the materials.

Based upon the results of this assessment, the materials used to fabricate the Urine Collection Pouch are considered biocompatible and appropriate for their intended use.

**8. Conclusion**

Based upon the information presented above it is concluded that the proposed Urine Collection Device is safe and effective for its intended use and is substantially equivalent to the predicate device.