K964219 (1 of 3)

Premarket Notification Section 510(k)	Summary of Safety and Effectiveness Information for the *ZIP™ Condom Catheter*

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Trade Name:** *ZIP™ Condom Catheter*

AUG 11 1997

Common Name: External male urine collection device

Classification Name: Device, Incontinence, Urosheath Type, Urine Collector and Accessories

2. **Establishment Name & Registration Number:**

Name: Goulter Medical, Inc.

Number: Pending

3. **Classification:**

§ 876.5250 Urine collector and accessories. (a) Identification. A urine collector and accessories is a device intended to collect urine. The device and accessories consist of tubing, a suitable receptacle, connectors, mechanical supports, and may include a means to prevent the back-flow of urine or ascent of infection. The two kinds of urine collectors are: (1) A urine collector and accessories intended to be connected to an indwelling catheter, which includes the urinary drainage collection kit and the closed urine drainage system and drainage bag; and (2) a urine collector and accessories not intended to be connected to an indwelling catheter, which includes the corrugated rubber sheath, pediatric urine collector, leg bag for external use, urosheath type incontinence device, and the paste-on device for incontinence. (b) Classification. (1) Class II (performance standards) for a urine collector and accessories intended to be connected to an indwelling catheter. (2) Class I (general controls) for a urine collector and accessories not intended to be connected to an indwelling catheter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of 820.180, with respect to general requirements concerning records, and 820.198, with respect to complaint files.

* UNDERLINE ADDED

Device Class: Class I for the proposed indications.

Classification Panel: Urology

Product Code: 78EXJ

Tier Class: Tier I Device

4. **Company Contact:**

Ms. Susan Clymer
One Embarcadero Center
Suite 1020
San Francisco, California 94111-3600
415.217.5656 - 415.217.5655 fax

5. **Special Controls:**

FDA Mandated Special Controls do not apply to this device.

6. **Substantially Equivalent Device(s):**

   1. **Mentor Freedom Cath®** - Self Adhering External Male Catheter
   2. **Everyday** - Self Adhesive Urinary External Catheter
   3. **Uri-Drain®** - Male Urinary Control Device
   4. **Uri-Drain®** - Leg Bag - Reusable Deluxe

7. **Device Description:**

The ***ZIP™ Condom Catheter*** has four basic elements: **1)** the condom/sheath with integral urine collection compartment; **2)** the Velcro-like band and support strap; **3)** the Application ring; and **4)** the specially designed male underpants brief.

The condom/sheath with integral urine collection compartment forms a bulbous tube approximately 10 ½ inches long. The tube is divided into two sections, the condom/sheath and the urine collection compartment. Non-return flow valves separate the condom/sheath portion from the urine collection compartment. The distal end of the urine collection compartment is affixed with a twist-open twist-closed stop-cock drain valve. The urine collection capacity is approximately 450 ml. Typical human urine output thus yields a time related capacity of about 4 to 6 hours.

A series of 4 sizes differing in sheath diameter and length will be offered. Specific name designators for the sizes are yet to be determined.

Design: The ***ZIP™ Condom Catheter*** expands upon existing male urine continence devices by first approaching the device as a "total" or "system" concept rather than just a collection of items originally developed for other urine collection purposes.

Only the essential elements of the ideal male urine continence system were considered. First, the system had to be easy to apply and use. Second, it should allow use of traditional male urination methods, i.e., the stand-up urinals found in public restrooms. Third, the system should be small enough to go unnoticed during the typical activities of daily living. Fourth, the system should have adequate capacity so that urine disposal intervals are not unreasonably short. Lastly, the system should be reusable and easily cleaned and sanitized.

This is a natural latex containing product. The ***ZIP™ Condom Catheter*** is made from the exact same natural latex formulation as the Everyday - Self-Adhesive Urinary External Catheter made by Hollister, Inc. The use of pure latex to construct the ***ZIP™ Condom Catheter*** requires the inclusion of certain FDA required cautionary statements. Latex containing devices must legibly bear an appropriate allergic reaction statement on the device labeling. In conformance with this FDA requirement, Goulter Medical, Inc. attaches a label containing the following cautionary statement to the device. **"This product is made from natural rubber latex which may cause allergic reactions in some individuals".**

The Cleared Indications for use are:

1. For penile attachment only
2. Non-Indwelling Urinary continence aid
3. Management of Urinary Incontinence
4. Urine Collection Device

Claims:

1. Unobtrusive
2. Reusable
3. Cost effective
4. Single piece system
5. Enhanced self-image and esteem
6. Improves social freedom
7. Lightweight
8. Less physically restrictive
9. Easy to use

8. Cleaning/Sterilization/Re-sterilization:

The device may not be sterilized or re-sterilized. Cleaning and washing using soap/detergent/water followed by surface disinfection may be employed using commercially available liquid germicidal agents. The device is reusable for a limited period of time. Generally, with reasonable care, the device may be used for about a week. Though in individual cases this period may be shorter or longer. Most often the limiting factor is the performance of the anti-reverse flow valves which tend to be performance affected by accumulating urine sediments and crystals. It is recommended that the device not be reused for more than a week and it should be replaced at once if the valves fail to operated properly.

9. Equivalence:

Based on the materials, intended uses, design and clinical effectiveness, the ***ZIP™ Condom Catheter*** is substantially equivalent to the previously referenced legally marketed male external urinary collection devices.

The feature comparison chart on the following page graphically demonstrates equivalence.

10. Feature Comparison Table:

FEATURE	*ZIP™ Condom Catheter*	Mentor Freedom Cath®	Everyday External Catheter	Uri-Drain®	SE?
Materials:	Medical Grade Latex	Latex	Identical Latex Formulation	Latex	Yes
Intended Use(s):	Non-Indwelling Male Urinary Continence Aid Management of Male Urinary Incontinence Male Bladder Training Aid to Improve Urinary Continence	Same			Yes
Design:	Single Piece Unit	Condom Only	Condom Only	Condom Only	Yes
Method of Operation:	One Way Flow to Collection Bag	Same	Same	Same	Yes
Bag:	Integral to Condom Sheath	Requires Secondary Leg Bag	Requires Secondary Leg Bag	Requires Secondary Leg Bag	Yes
Bag Capacity:	Approx. 450 m/L	About 1 Liter	About 1 Liter	About 1 Liter	Yes
Underpant:	Male Brief W/ Pouch	NA	NA	NA	No
How Secured:	Velcro Band & Strap	Adhesive Sheath	Spiral Foam Band	Spiral Foam Band	Yes
Sizes:	4	4	3	3	Yes
Additional Items Needed to Use the Device:	None - Sold Complete	Leg Bag Connectors Tubing Adhesive tube Holder	Leg Bag Connectors Tubing Tube clamp	Leg Bag Connectors Tubing Adhesive tube Holder	No
Manufacturer:	Goulter Medical	Mentor	Hollister	Sherwood Medical	Yes
Product Code:	78EXJ	78EXJ	78EXJ	78EXJ	Yes
K - Number	K964219	Preamendment	Preamendment	Preamendment	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 11 1997

Goulter Medical, Inc.
c/o Buckman Company, Inc.
Mr. David W. Schlerf
1000 Burnett Avenue, Suite 450
Concord, California 94520

Re: K964219
Zip™ Condom Catheter
Dated: July 12, 1997
Received: July 21, 1997
Regulatory Class: I
21 CFR §876.5250/Product Code: 78 EXJ & EYZ

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K964219

Device Name: *ZIP™ Condom Catheter*

Indications For Use:

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2. Non-indwelling Urinary Continence Aid
3. Management of Urinary Incontinence
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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin M. Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964219

Prescription Use ___ OR Over-The-Counter Use √

(Per 21 CFR 801.109) (Optional format 1-2-96)