This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

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GUIDANCE FOR THE CONTENT OF PREMARKET NOTIFICATIONS FOR Urine Drainage Bags

A urine drainage bag is described in the FDA regulation, 21 CFR 876.5250(a), Urine Collector and Accessories, as 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 backflow 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." The classification for this device is Class II if used with an indwelling catheter or Class I if used with an external catheter as stated in 21 CFR 876.5250(b).

Examples of devices within this generic type include:

Class	Procode	Device Name
I	FAQ	Urine Collection Leg Bag for External Use
I	FOC	Newborn Urine Collection Bag
I	EXJ	Urosheath Type Incontinence Device
I	EXI	Paste-On Device for Incontinence
I	EYT	Corrugated Rubber Sheath for Non-Indwelling Catheter
II	EYZ	Closed Urine Drainage System for Indwelling Catheter
II	FCN	Urinary Drainage Collection Kit for Indwelling Catheter
II	KNX	Urine Collector (and Accessories) for Indwelling Catheter
II	FFH	Pediatric Urine Collector for Indwelling Catheter

The primary reference for the information required to be in a premarket notification (510(k)) for a medical device is set forth in 21 CFR 807.87. The purpose of this regulation is to provide adequate documented information to determine substantial equivalence to a device in commercial distribution. Substantial equivalence is to be established with respect to, but not limited to, intended use, design, materials, performance, safety, effectiveness, labeling, and other applicable characteristics.

In addition to the information specified in the DRAERD "Draft Guidance for the Content of Premarket Notifications" which is available from the Center for Devices and Radiological Health's Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597, FDA recommends that each premarket notification for a urine drainage bag and accessories include the following information in order to ensure that the submission is complete and will permit a determination of substantial equivalence:

JUN - 7 1994

I. Device Description

The physical description of each urine drainage bag and its accessories to be marketed should be provided in the form of a labeled diagram, photograph/ picture, schematic, etc., which includes the name and addresses the function of all internal/external, assembled/ unassembled, interchangeable, etc., parts of the urine drainage bag and accessories.

The physical description should include the specific fluid volume of the urine drainage bag and accessories, and the unique features of the bag (i.e., backflow valve – air trap, flutter, one-way; built-in urometer; lack of drain; absorbent materials; etc.). The physical description should also identify any parts which are disposable.

If the urine drainage bag is sold in a set that includes accessories, these accessories should be identified and reviewed along with the urine drainage bag and require the same types of information as stated above. These accessories might include a secondary drainage bag for overnight drainage. Labeling should state whether the accessory is intended for single use and disposable or whether it is reusable.

II. Labeling

A. A label includes any identification on the urine drainage bag and on the package in which it is stored and shipped. The device label should include the device name, corporation name, address, and telephone number. The package label should include all of the above, as well as sterility status, expiration date, disposable/ single use, quantity enclosed, size, etc. The label of the device packaging should include the prescription device statement as outlined in 21 CFR 801.109(b)(1): "CAUTION: Federal law restricts this device to sale by or on the order of a physician."

B. Device labeling for the urine drainage bag and its accessories includes the intended use, a description of the device, and directions for use.

1. The directions for use should contain comprehensive instructions on how to prepare the urine drainage bag for use, how to operate the urine drainage bag, and which parts are single use/disposable or reusable. If reusable, provide instructions on how to clean, disinfect, and/or sterilize the urine drainage bag. If the device does not have a drain, the instructions should provide a minimum time between replacements (e.g., at least every 24 hours or when the bag becomes full). The directions should address positioning of the urine drainage bag to prevent urine backflow (i.e., keep the bag below the level of the patient's bladder).

2. Applicable contraindications, warnings, and precautions should be included in the labeling of the device.

3. All claims should be supported, and claims concerning reduced possibility for infection or contamination may need to be supported by clinical data.

C. Advertisements or promotional literature for the urine drainage bag should be provided. Literature or labeling may not imply approval by FDA in any manner. Guidance on labeling issues is described in Bluebook Memo G91-1 "Device Labeling Guidance (3/18/91)" which is available from DSMA at the telephone number referenced above.

III. Bench Testing

The following studies and results should be provided to demonstrate the substantial equivalence of the urine drainage bag with respect to functional performance.

Typical tests include:

water backflow pressure through the anti-reflux valve;
24-hour inversion leakage test results;
standing column test to examine the drainage efficiency of bag; and
drainage time test to ensure a reasonable length of time until the bag empties.

If the urine drainage bag contains a fluid absorbent material the following tests should be conducted:

confirmation of the amount of material in the drainage bag; and
the maximum amount of fluid the material will absorb.

If the urine drainage bag contains an adhesive, the adhesive should be demonstrated to be sufficiently strong to attach the device to the patient yet also readily and safely removable.

IV. Biocompatibility

Biocompatibility information specifically concerning the materials used in the urine drainage bag must be addressed. Materials such as adhesives, if used, should have the following tests performed:

identification of the chemical composition of the adhesive; and

all appropriate tests identified in the
Tripartite Biocompatibility Guidance for either:

1) external devices that contact a breached or compromised surface; or
2) an externally communicating device that contacts intact natural channels, depending on urine drainage bag design and intended use.

Biocompatibility of absorbent materials, if used in the urine collection bag, must also be addressed. The complete chemical composition of the absorbent materials should be identified, and the biocompatibility tests specified in the Tripartite Biocompatibility Guidance for an externally communicating device that contacts intact natural channels should be provided.

V. Sterilization

Complete information regarding urine drainage bags and accessories that are sold sterile should be provided. Refer to the DRAERD Premarket Notification 510(k) Screening Checklist and accompanying explanation document for details.

In addition, guidance on sterility issues is provided in ODE Bluebook Memo K90-1 "510(k) Sterility Review Guidance (2/12/90)" which is available from DSMA at the telephone number referenced above.

If the urine drainage bag contains a fluid absorbent material and is intended for use with indwelling catheters, the 510(k) should address whether the material is sterilized while in the bag, and whether the sterilization process causes any changes in the chemical composition and absorbent properties of the material which could effect device safety.

VI. Modifications

For a device that has undergone a change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the 510(k) should include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device, as described in 21 CFR 807.87(g).

Significant modifications should be supported by a rationale for the modification with supporting documentation, possibly including clinical or other valid scientific studies which

demonstrate that these differences do not affect safety and effectiveness, as described in 21 CFR 807.87(f).

The description of all urine drainage bags and accessories should include any significant changes or modifications from the predicate device that could affect safety, effectiveness, or intended use. Provide any bench, animal, clinical, functional, in vitro, and/or any other testing data to support your claims. Provide certification regarding compliance with voluntary standards, if applicable.

Additional guidance concerning device modifications is also available in the draft guidance titled, "Deciding When to Submit a 510(k) for Change to an Existing Device (4/8/94)" which is available from DSMA at the telephone number referenced above.

For further information contact:

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