MEDLINE

Medline Industries, Inc.

One Medline Place
Mundelein, Illinois 60060.4486

1.847.949.3109
1.800.950.0128
Fax 1.847.949.2643

Corporate Quality Assurance/Regulatory Affairs

SUMMARY OF SAFETY AND EFFECTIVENESS

K972887
P1071

July 31, 1997

DEC 11 1997

1. COMPANY INFORMATION:
Dynacor Manufacturing
A Division of Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Registration #: 1417592
Phone: (847) 949-5500 x1131
Fax: (847) 949-2643
Contact Name: Christine M. Galea
Contact Title: Corporate Regulatory Affairs

2. DEVICE NAME: Urine Collection Leg Bag for External Use
PROPRIETARY NAME: Premium Leg Bag, Fabric-Bac Leg Bag, Urinary Leg Bag
COMMON NAME: Leg Bag
CLASS: I (for devices not intended to be connected to an indwelling catheter)
II (for devices intended to be connected to an indwelling catheter)

3. SUBSTANTIAL EQUIVALENCE:
Medline claims substantial equivalence to:
Medline's Urine Collector Leg Bag
Bard's Leg Bags (K780032)

These new devices are identical to what Medline is currently marketing. The only difference between the devices that are currently on the market and what we intend to market is in the labeling.

4. DESCRIPTION:
Medline Leg Bags are vinyl pouches with sterile fluid paths and adjustable comfort straps. This device is attached to the leg of an incontinent person and used to collect urine. This device may be used with an indwelling catheter or an external catheter. A leg bag provides the catheterized person with greater mobility and are usually worn during the day and are replaced at night with a standard urinary drainage bag.

5. INTENDED/INDICATIONS FOR USE:
These devices are indicated for use by incontinent persons or persons with other medical conditions that warrant the use of a leg bag on the advice of a physician and are intended to collect urine. They may be connected to either an indwelling or non-indwelling catheter.

6. TECHNOLOGICAL CHARACTERISTICS:
There are no technological characteristics to the new device. The only change Medline is making is in the labeling.

7. CLINICAL TESTS:
There are no clinical studies that have been performed on these devices, both for the predicate and the new devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 1997

Ms. Christine M. Galea
Corporate Regulatory Affairs
Medline Industries, Inc.
One Medline Place
Mundelein, Illinois 60060-4486

Re: K972887
Urine Collection Leg Bag
Dated: November 12, 1997
Received: November 18, 1997
Regulatory class: II and I
21 CFR §876.5250/Product code: 78 KNX and FAQ

Dear Ms. Galea:

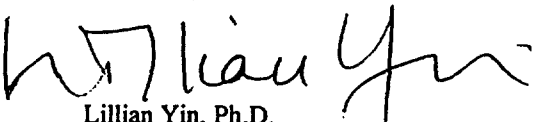
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

INTENDED USE

510(k) Number (if known): (N/A)

Device Name: Medline Premium Leg Bag, Fabric-Bac Leg Bag, Urinary Leg Bag

Indications for Use:
These devices are indicated for use by incontinent persons or persons with other medical conditions that warrant the use of a leg bag and are intended to collect urine. They may be connected to either an indwelling or non-indwelling catheter.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972587

(Optional Format 1-2-96)