

JUN 10 1997

K 970946
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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS - K970946

May 6, 1997

SUBMITTER INFORMATION:

Medline Industries, Inc.

One Medline Place

Mundelein, IL 60060

1-847-949-3109

Establishment Registration Number: 1417592

Contact Person: Christine Galea, Corporate Regulatory Affairs Associate

REGULATORY INFORMATION

Device Name:	Y-Type TUR/Bladder Irrigation Set
Proprietary:	Medline Y-Type TUR/Bladder Irrigation Set
Common:	Urological Irrigation System and/or Tubing Set
Panel:	78 Gastroenterology & Urology
Class:	II
Procode/Classification:	LJH 78 (Unclassified)
Special Controls:	None established

DEVICE DESCRIPTION:

This device is comprised of vinyl tubing with a catheter adapter at one end and "spikes" with protectors at the "Y" shaped end. There are pinch clamps on each of the "Y" shaped ends below the spikes. On the single tubing there is a drip chamber. Directly below the drip chamber is a roller clamp. There is a latex rubber connecting tube, approximately 5-6 inches in length attached to the catheter adapter. This latex rubber tubing is removable.

INTENDED USE:

A urological irrigation system is intended for the infusion of sterile solutions into the bladder to cleanse or evacuate the contents of the bladder. Medline Y-Type TUR/Bladder Irrigation Set is indicated for use in transurethral resection (prostate or bladder surgery) as a means of continuous irrigation of the bladder. This product contains natural rubber latex which may cause allergic reactions in some individuals. For use with sterile saline or sterile water only. Do not use with plasma products. Not intended for reuse.

SUBSTANTIAL EQUIVALENCE

Medline Industries, Inc. claims substantial equivalence to Vital Concepts, K934382 and Baxter Healthcare's Y-Type TUR/Bladder Irrigation Set, which is pre-amendment exempt.

Medline Y-Type TUR/Bladder Irrigation set is similar to other Y-Type TUR/Bladder Irrigation sets currently being marketed. They are made of smooth vinyl tubing, have pinch and roller clamps, spikes with protectors and a catheter adapter. The significant difference is the length of the latex tubing and the length of the vinyl tubing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 1997

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

Re: K970946
Medline Y-Type TUR/Bladder Irrigation Set
Dated: May 29, 1997
Received: May 30, 1997
Regulatory class: unclassified
Product code: 78 LJH

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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

K970946

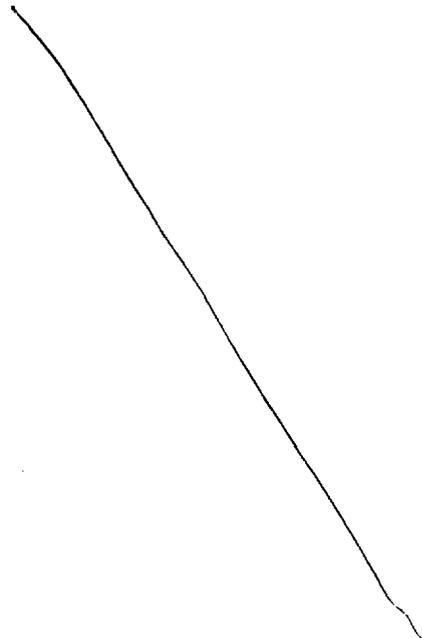
510(k) Number (if known): K970946

Device Name: Medline Y-Type TUR/Bladder Irrigation Set

Indications For Use:

Medline Y-Type TUR/Bladder Irrigation Set is Intended for the infusion of sterile solutions into the bladder to cleanse (evacuate) the contents of the bladder. It is also indicated for use in transurethral resection (prostate or bladder surgery) as a means of continuous irrigation of the bladder.

It is intended to be used with sterile solutions only. Not intended for reuse.



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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

OR

Over-The-Counter Use

Robert D. Sathberg
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

(Optional Format 1-2-96)

510(k) Number K970946