

K 974600
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**510(k) Summary of Safety and Effectiveness
UroMed Patch**

Company Name

MAR 31 1998

UroMed Corporation
64 A Street
Needham, MA 02194

Official Contact

Frederick Tobia
Director, Clinical and Regulatory Affairs

Device Name

Proprietary Name: UroMed Patch
Common Name: Urethral Patch
Classification Name(s): Device, urethral occlusion, for incontinence

Predicate Devices used for Substantial Equivalence

Miniguard Patch (Impress Softpatch) Advanced Surgical Intervention K954215
Now UroMed Corporation

Intended Use

The UroMed Patch is indicated for the prevention or decrease of episodes of urine leakage in women with stress urinary incontinence.

Indications for Use

The UroMed Patch is indicated for the prevention or decrease of episodes of urine leakage in women with stress urinary incontinence.

Description

The UroMed Patch is a single use, disposable foam pad that is coated on one side with an adhesive gel. The patch is worn over the urethra between times of urination. The product is intended to prevent urine from escaping the environs of the urethra, and is replaced each time the patient urinates.

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Summary of Standards Achieved

The UroMed Patch was designed and tested to meet the following standards:
ISO 10993

Summary of Testing

In-Vitro Testing

The UroMed Patch and the component materials have been tested for biocompatibility, toxicity, cytotoxicity, bacteriostasis/fungistasis, and skin sensitivity. The testing exceeds the guidelines set forth in ISO 10993 for a chronically used mucosal membrane devices. The results indicate the materials and product are biocompatible, non-toxic and well tolerated by subcutaneous tissue.

Clinical Testing

The UroMed Patch has been extensively tested for its safety and efficacy in decreasing the number of urinary leakage episodes in women with incontinence. In addition, the UroMed Patch has been tested to ensure the device can be used outside the supervision of a licensed practitioner, and adequate directions for use have been prepared.

The following observations were noted in regards to product efficacy:

Parameter	Control	After 12 Weeks	Improvement	p-value
Mean Number of Leakage Episodes per week	14.18	4.89*	65.5%*	0.0001
Perceived Severity of Leakage Scale: 0=not at all; 3=severe; 13 activities rated – total possible score of 39	11.02	3.18	71.1%	0.0001
Impact on Quality of Life Subjects rated degree to which urinary leakage had a negative effect on 26 activities for a maximum possible score of 78 (0 = not at all, 3 = severe)	10.42	2.98	71.4%	0.0001
Leakage (grams/hour)	1.31	0.51	61.1%	0.0001

***NOTE:** In reviewing the average number of leakage episodes reported by the patients at weeks 9, 13 and 17 (5.69 leakage episodes) as compared with the control period (14.18 leakage episodes), there was an improvement of 60%.

To provide clinical safety assurance of the UroMed Patch, the effects of use on bladder function, microbiology and dermatology were evaluated. There were no clinically significant changes noted. The sole event which may be associated with use of the UroMed Patch was a minor increase in the incidence of subject reported symptoms of irritation, characteristic of minor irritation associated with use of any topical device.

Labeling and self screening studies were conducted to assure patients could self-diagnose the type of incontinence, and correctly place the device by using instructions for use.

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Conclusion

Based on these data the UroMed Patch has been shown to be safe and effective for its intended use.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

APR 26 2010

Mrs. Nancy C. MacDonald
Manager, Clinical & Regulatory Affairs
UroMed Corporation
65 A Street
NEEDHAM MA 02194

Re: K974600

Trade/Device Name: UroMed Patch
Regulation Number: 21 CFR§ 876.5160
Regulation Name: Urological clamp for males
Regulatory Class: I
Product Code: MNG
Dated: March 9, 1998
Received: March 10, 1998

Dear Mrs. MacDonald:

This letter corrects our substantially equivalent letter of March 31, 1998.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

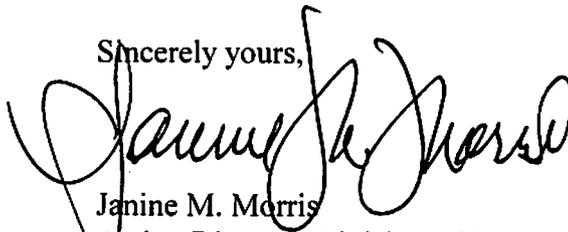
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**510(k) Premarket Notification
UroMed Patch**

510(k) Number (if known): K974600

Device Name: UroMed Patch

Indication for Use:

The UroMed Patch is indicated for the prevention or decrease of episodes of urine leakage in women with stress urinary incontinence.

(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

Daniel D. Rath...
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974600

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