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510(k) Summary of Safety and Effectiveness
UroMed Alternative Bladder Control Continence Device

Company Name and Address

UroMed Corporation
64 A Street
Needham, MA 02194

AUG - 1 1997

Official Contact

Nancy MacDonald
Manager, Clinical & Regulatory Affairs

Device Name

Proprietary Name:	UroMed Alternative Bladder Control Continence Device (ABC)
Common Name:	Penile Clamp/Urological Clamp
Classification Name:	21 CFR § 876.5160 Urological Clamp for Males (Class I)

Predicate Devices used for Substantial Equivalence

The following are predicate devices used for substantial equivalence. The devices are currently marketed with either pre-amendment status or current PreMarket notification numbers:

Product Name	Manufacturer	510(k) #
Cap-Aid Continence Device	NEBL Inc.	K964580
C^3 Male Continence Device	Dacomed Corp.	K885323
Male Assistant	Insight Medical Corp.	K952841
Cunningham Clamp	Bard	pre-amendment

Intended Use

The UroMed ABC device is intended to prevent or reduce episodes of male urinary incontinence. Please refer to Section 7 for the device Instructions for Use.

Indications for Use

The UroMed ABC device is indicated to prevent or reduce episodes of male urinary incontinence.

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Design Description

The UroMed ABC device is a urological clamp designed to significantly reduce the leakage of urine by occluding the urethra. The ABC device is clamped on the glans of the penis to provide less compression, yet the same continence as those urological clamps that are placed on the shaft of the penis.

Summary of Standards Achieved

ISO-10993: "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing".

ASTM D2979-88: "Standard Test Method for Pressure Sensitive Tack of Adhesives Using an Inverted Probe Machine".

Performance Data

Bench tests were conducted to evaluate the tack force and the peel force of the ABC device adhesive. The tack force of the adhesive for the ABC device was compared with adhesive for another commercially available male incontinence device. The results indicate that the tack of the UroMed ABC device adhesive provides a consistent and reliable adherence. The peel force of the ABC device adhesive was evaluated on human skin. Tests results indicate that. . . .

Summary

In summary, the UroMed ABC device a type of urological clamp as defined by 21 CFR §876.5160 and is substantially equivalent to the following devices: Cap-Aid Continence Device, the C^3 Male Continence Device, the Male Assistant and the Cunningham Incontinence Clamp. All five (5) devices have the same intended use: to prevent urinary leakage in males. Information presented in the 510(k) demonstrates that the UroMed ABC device does not raise new questions of safety or effectiveness and is as safe and effective as other legally marketed devices. Therefore, UroMed believes that FDA should determine that the ABC device is substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 1 1997

Ms. Nancy C. MacDonald
Manager, Clinical & Regulatory Affairs
UroMed Corporation
64 A Street
Needham, Massachusetts 02194

Re: K971992
UroMed® Alternative Bladder Control Device
Dated: May 28, 1997
Received: May 29, 1997
Regulatory class: I
21 CFR §876.5160/Product code: 78 FHA

Dear Ms. MacDonald:

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,

William Yin

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 (if known): K971992

Device Name: UroMed Alternative Bladder Control Device

Indications For Use:

To prevent or reduce episodes of male urinary incontinence.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971992

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

(Optional Format 1-2-96)