

K980717

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510(k) Summary of Safety and Effectiveness
UroMed Sling Kit

Company Name

UroMed Corporation
64 A Street
Needham, MA 02194

Official Contact

Nancy C. MacDonald
Manager, Clinical and Regulatory Affairs

Device Name

Proprietary Name: UroMed Sling Kit
Common Name: Sling Kit
Classification Name: 21 CFR § 876.4730 Manual Surgical Instruments

Predicate Devices used for Substantial Equivalence

<u>Device</u>	<u>Premarket #</u>
Cook Loop Retriever	K933698
Cook Stamey Needle	Pre-Amendment
Cook Fascial Dilator	Unknown
Acufex Suture Retriever	K881224 and K926036

Intended Use

The UroMed Sling Kit is intended to be used in a suburethral sling procedure for the alleviation of involuntary leakage of urine due to urinary incontinence in adult women.

Indications for Use

The UroMed Sling Kit is indicated for use by the surgeon for placing a urethral sling. The kit provides instruments to help the surgeon place the sling beneath the urethra. The kit will be used in suburethral sling procedures for female urinary incontinence due to urethral hypermobility and/or intrinsic sphincter deficiency.

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Description

The UroMed Sling Kit is a single use, manual surgical kit for use during suburethral sling procedures. The kit will be used to place a sling (autograph, allograph, or synthetic) beneath the urethra in suburethral sling procedures.

The kit is comprised of two needles, two sheaths and two loops.

The kit components are constructed out of the following materials:

Needle: Surgical Stainless Steel, meeting ASTM Specification F899-84, with a handle constructed of Polyethylene Terephthalate (PET-P).

Sheath: Polyethylene

Loop: Surgical Stainless Steel, meeting ASTM Specification F899-84, with Polyethylene shaft

Summary of Standards Achieved

ASTM F899-84 Standards for Stainless Steel Billet, Bar and Wire for Surgical Instruments.

ISO 10993-1, "Biological evaluation of medical devices -- Part 1: Guidance on selection of tests".

Summary

In summary, the UroMed Sling Kit is substantially equivalent to legally marketed devices. Quality System Controls assure the device is substantially equivalent to the predicate devices with respect to its performance, safety, and effectiveness.



MAY 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Nancy C. MacDonald
Manager, Clinical and Regulatory Affairs
Uromed Corporation
64 A Street
Needham, MA 02194

Re: K980717
Uromed® Sling Kit
Dated: February 20, 1998
Received: February 24, 1998
Regulatory class: II
21 CFR §884.4530/Product code: 85 KNA

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 requirements, 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/dsma/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

510(k) Premarket Notification
UroMed Sling Kit

510(k) Number (if known): K980717

Device Name: UroMed Sling Kit

Indication for Use:

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(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 R. Rathjens
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

UroMed Sling Kit - 510(k)
2/20/98

510(k) Number K980717