

**510(k) Summary of Safety and Effectiveness
UroMed® Needle Grasper**

Company Name

UroMed Corporation
64 A Street
Needham, MA 02194

Official Contact

Frederick Tobia
Director, Clinical and Regulatory Affairs

Device Name

Proprietary Name: UroMed® Needle Grasper
Common Name: Endoscope/Laparoscope and Accessories - Needle Driver
Classification Name(s): 21 CFR § 876.1500 Endoscope and Accessories
~~21 CFR § 876.4730 Manual Surgical Instruments~~

Predicate Devices used for Substantial Equivalence

Cook Endoscopic Grasping Forceps
Laurus Medical Suture Placement System

K933698
K932533

K924196

Intended Use

The UroMed Needle Grasper is intended to be used during endoscopic/laparoscopic surgical procedures to hold a suture needle allowing for suture passing.

Indications for Use

The UroMed Needle Grasper is indicated for use by the endoscopic/laparoscopic surgeon for internal suturing under direct vision. The device is designed to grasp a suture needle for manipulation by the surgeon. The device will be used in bladder neck suspension procedures for female urinary incontinence due to urethral hypermobility.

Description

The UroMed Needle Grasper is a single use, manual surgical instrument for use during endoscopic/laparoscopic surgical procedures. The Needle Grasper will be used through an endoscopic/laparoscopic operating channel or under open surgical procedures. The instrument will be used to place and pass suture in bladder neck suspension procedures (urethropexy).

The device is constructed out of Surgical Stainless Steel with a handle constructed of medical grade polymers.

Summary of Standards Achieved

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

USP Class VI Biocompatibility.

Summary

In summary, the UroMed Needle Grasper 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frederick Tobia
• Director, Clinical and Regulatory Affairs
UroMed Corporation
64 A Street
Needham, Massachusetts 02194

Re: K974137
Trade Name: UroMed® Needle Grasper
Regulatory Class: II
Product Code: KOG
Dated: October 31, 1997
Received: November 3, 1997

Dear Mr. Tobia:

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.

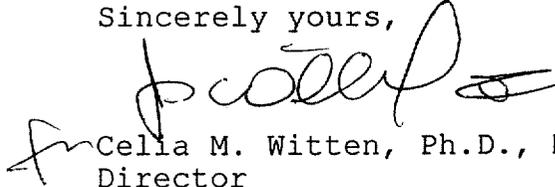
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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) 594-4595. 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,



Cella M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K974137

**510(k) Premarket Notification
UroMed® Needle Grasper**

510(k) Number (if known): K97

Device Name: UroMed® Needle Grasper

Indication for Use: The UroMed Needle Grasper is indicated for use by the endoscopic/laparoscopic surgeon for internal suturing under direct vision. The device is designed to grasp a suture needle for manipulation by the surgeon. The device will be used in bladder neck suspension procedures for female urinary incontinence due to urethral hypermobility.

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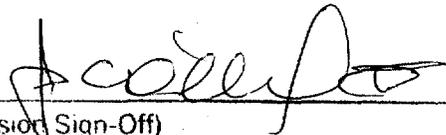
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

UroMed® Needle Holder - 510(k)
10/31/97



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

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K974137