

AUG 20 1998

510(k) Summary

Pursuant to 512(i)(3)(A) of the Food, Drug and Cosmetic Act, MedWorks Corp. is required to submit with this Premarket Notification either an "...adequate summary of any information respecting safety and effectiveness or state that information will be made available upon request of any person." MedWorks chooses to submit a summary of the safety and effectiveness information. The summary is as follows:

Trade Name: MedWorks Urinary Incontinence Surgical Devices

Sponsor: MedWorks Corp.
2400 Crittenden Drive
Louisville, KY 40217
Resistration #1530618

Device Generic Name: Urinary incontinence surgical devices

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices: K971791 - Urethropexy Suture Placement Kit
K971796 - Mini-Laparotomy MMK Kit
K971797 - Laparoscopic Burch Set
K963076 - Laparoscopic MMK Kit
K971801 - Mini-Laparotomy Burch Set
K971802 - Urethropexy Suture Placement Set

Manufactured by:
MedWorks Corp.
2400 Crittenden Drive
Louisville, KY 40217

Product Description: The devices described in this 510(k) are surgical procedure kits intended for use in urethropexy procedures, and include components such as suture placement templates, bone anchors, bone drills, syringes, suture retrievers and suture cutters.

Indications for Use:

MedWorks Urinary Incontinence Surgical Devices are indicated for use in urethropexy surgical procedures for bladder neck suspension to correct female stress urinary incontinence due to urethral hypermobility.

Safety and Performance:

This submission is a Special 510(k): Device Modification as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), MedWorks has provided certification of compliance to 21 CFR 820.30 Design Control requirements, and a description of the internal Risk Analysis procedure. Validation testing including pull testing, bond integrity testing and simulated use performance testing is included in Design Validation and Verification planning.

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Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the MedWorks Urinary Incontinence Surgical Devices have been shown to be safe and effective for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 1998

Medworks Corporation
c/o Ms. Pamela Papineau
Delphi Medical Device Consulting
50 Brewster Street
Pawtucket, Rhode Island 02860

Re: K982626

Modified Foley Catheter for Medworks Urinary Incontinence Surgical Device Kits:
Urethropexy Suture Placement Kit, Mini-Laparotomy Kit, Laparoscopic Burch Kit,
Laparoscopic MMK Kit, and Mini-Laparotomy Burch Kit

Dated: July 24, 1998

Received: July 28, 1998

Regulatory Class: II

21 CFR 876.5130/Procodes: 78 EZL

Dear Ms. Papineau:

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In

addition, the Food and Drug Administration (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.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used in the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.
2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

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 the 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,



for

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): K982626

Device Name: MedWorks Urinary Incontinence Surgical Devices: Urethropexy Suture Placement Kit, Mini-Laparotomy MMK Kit, Laparoscopic Burch Kit, Laparoscopic MMK Kit, Mini-Laparotomy Burch Kit

Indications for Use:

MedWorks Urinary Incontinence Surgical Devices are indicated for use in urethropexy surgical procedures for bladder neck suspension to correct female stress urinary incontinence due to urethral hypermobility.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R. Rathling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982626

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use