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OCT 2 5 2004

510(K) SUMMARY

URO Pro

I. Applicant:

W.O.M. WORLD OF MEDICINE AG
Alte Poststraße 11
96337 Ludwigsstadt
Germany

Phone number: + 49 30 39981610
Fax number: + 49 30 39981593

Establishment registration number: 8043980

Official Correspondent: Susanne Raab
119 South Street
Hingham, MA 02043

Phone number: 781 749 4656

Date Prepared: **September 2, 2004**

II. Device Names:

1. Classification Name: URO Pro
2. Common or Usual Name: Urological Irrigation System
3. Proprietary Name: Urological Irrigation System and Tubing Set

III. Product Classification:

Product Code: LHJ
Device Class: II

IV. Predicate Devices:

- **Hysteroscopy Pump HM4** (K022449) manufactured by W.O.M. WORLD OF MEDICINE AG
- **Karl Storz Uromat** (K940983) manufactured by Karl Storz Endoscopy-America, Inc.
- **ENDO FMS Urology** (K980808) manufactured by Future Medical Systems, Inc.

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V. Intended Use:

The URO Pro is an irrigation roller pump intended for the infusion of sterile solutions into the ureter and upper urinary tract during diagnostic and/or therapeutic endoscopic urologic procedures. It is indicated for the infusion of sterile solutions through an endoscope into the urogenital tract to irrigate the ureter or upper urinary tract in a controlled manner and to improve visibility of the surgical field during urologic procedures.

VI. Device Description:

The URO Pro is a microprocessor controlled pump which functions according to the peristaltic principle and incorporates the following major components and features: a power supply, a main cable, a roller wheel, a pump head, various setting keys and display elements. The pump head is designed with two pressure sensors to perform redundant pressure measurement. A software controlled active pressure reduction ensures the conformity of the preset nominal pressure value with the actual measured pressure. In addition, the URO Pro is designed with several alarms to inform the operator in case of an overpressure.

VII. Substantial Equivalence:

The URO Pro is substantial equivalent to the Hysteroscopy Pump HM4 in regards to its design and characteristics. Both the URO Pro and the Hysteroscopy Pump HM4 use the same basic principles of operation, incorporate the same technological characteristics and are used with the same tubings sets. Although there are some technological differences between the devices, these differences to not raise new questions of safety and effectiveness considering the different intended use of the devices. In addition, the URO Pro is substantial equivalent to the Karl Storz Uromat (K940983) and the ENDO FMS Urology (K980808). Specifically, the URO Pro like the Karl Storz Uromat and ENDO FMS Urology is intended to be used for the infusion of sterile solutions into the ureter and upper urinary tract during diagnostic and/or therapeutic endoscopic urological procedures. The URO Pro has also similar technological characteristics and principles of operation as the Karl Storz Uromat and ENDO FMS Urology and the minor technological characteristics do not raise any new issues of safety or effectiveness.

VIII. Performance Data:

The device complies with the International Standard IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 5 2004

W.O.M. WORLD OF MEDICINE AG
c/o Ms. Susanne Raab
Regulatory Consultant
119 South Street
HINGHAM MA 02043

Re: K042457
Trade/Device Name: URO Pro
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LJH
Dated: September 2, 2004
Received: September 10, 2004

Dear Ms. Raab:

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 application (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 (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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K042457

Device Name: **URO Pro**

Indications for Use:

The URO Pro is an irrigation roller pump intended for the infusion of sterile solutions into the ureter and upper urinary tract during diagnostic and/or therapeutic endoscopic urologic procedures. It is indicated for the infusion of sterile solutions through an endoscope into the urogenital tract to irrigate the ureter and upper urinary tract in a controlled manner and to improve the visibility of the surgical field during urologic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescripition Use ✓ OR Over-The-Counter Use_____
(Per 21 C.F.R. 801.109)

(Optional Format 3-10-98)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042457