K967276 1/3

Richard Wolf Medical Instruments Corporation

NOV 25 1997

353 Corporate Woods Parkway
Vernon Hills, Illinois 60061
Telephone: 847.913.1113
Fax: 847.913.1488

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: October 25, 1996
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913-1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913-0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:	
Trade name: Endoscopic Hysterectomy and Uterus manipulator	Model number: 8370.501/.511/.512 /.513, 8983.011 /.111 /.201
Common name:	Classification name: Endoscope and accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1	1 valtchev manipulator	1 European Patent Applicant 94103496.9
2	2 RUMI	2 Cooper Surgical
3 pre-enactment	3 8370.00	3 Richard Wolf Medical Instruments
4	4 26201A	4 Storz
5	5 24945A	5 Storz
6 pre-enactment	6 8991.02	6 Richard Wolf Medical Instruments
7 pre-enactment	7 4837 C	7 Richard Wolf Medical Instruments
8	8 24945AO	8 Storz
9	9 24945E	9 Storz

1.0 Description

The Endoscopic Hysterectomy instruments and Uterus manipulator are designed to remove the uterus through the vagina. The obturator can be introduced into the vagina through the tube. The vaginal tube is gas tight.

The changeable distal tip of the uterus manipulator is deflectible so that the uterus can be moved in optimal operation position. The jaw with the teeth fixes the cervix part on the manipulator and can be locked and released with the locking device (17). When the turned handle is moved clockwise, the distal tip goes in the deflected angle. When the luer sealing cap is removed the instrument can be cleaned by rinsing.

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2.0 Intended Use

The instrument set consisting of vaginal tube, obturator (mandrin) and instrumentation inserts in combination with the uterus manipulator and uterus probe is used to support LAVH (laparoscopically assisted vaginal hysterectomy).

2.1 Contraindication

Contraindications described in the relevant literature must be observed.

Diagnosis and treatment of a pelvic mass that is too large to fit intact into an impermeable sack (≤8 x 5 in.).

Laparoscopic Hysterectomy is not indicated when vaginal hysterectomy is possible.

The medical status of the patient may prohibit surgery. Anemia, diabetes, lung disorders, cardiac disease, and bleeding diathesis must be evaluated before surgery. Age should rarely be a deterrent. Cesarean hysterectomy is an absolute contraindication. Placenta accreta, uterine atony, unspecified uterine bleeding, and uterine rupture are relative contraindications for peripartum hysterectomy at present. Another contraindication might be stage III ovarian cancer that requires a large abdominal incision.

Inexperience of the surgeon is a contraindication to the laparoscopic approach.

3.0 Technological Characteristics

- autoclavable
- speziell shaped tubal tip
- gas tightness
- gas tight instrumental ports

4.0 Substantial Equivalence

The basic design of the tube and obturator are equivalent to pre enactment devices from R.Wolf and equivalent to existing competitive devices. There are some modifications in dimension e.g. length, diameter; contour, function and working insert for its intended use in LAVH.

The manipulator is based on pre enactment devices from R.Wolf, but is changed in design and now used through the tube for its intended use in LAVH and is equivalent to competitive devices.

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5.0 Performance Data

Mechanical stress test of the vaginal tube shows, that the bayonet locking system is tight after 100,000 cycles of opening and closing.

Mechanical test of the uterus manipulator shows that the mechanical resistance of the hinch is strong enough for the manipulating of the uterus.

The steam sterilization in the clinical use and the tests performed by Richard Wolf shows, that the steam sterilization has no influence to the quality of the endoscopic hysterectomy instruments and uterus manipulator, when using the fractional method.

6.0 Clinical Tests

No clinical tests performed.
(see literature Dr. Reich „The Role of Laparoscopy in Hysterectomy", Advances in Obstetrics and Gynecology, vol.1 1994, Mosby-Year Book, Inc.).

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instruction manual.

By: Robert L. Casarsa Date: Oct 22, 96

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1997

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K964276
Endoscopic Hysterectomy and Uterus Manipulator
(see attached list for model names and numbers)
Dated: August 25, 1997
Received: August 29, 1997
Regulatory class: II
21 CFR §884.4160/Product code: 85 HEW
21 CFR §884.4530/Product code: 85 HDP

Dear Mr. Casarsa:

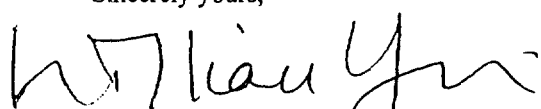
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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):_____ P192

Device Name: Endoscopic Hysterectomy and Uterus Manipulator

Indications for Use:

Indications for Use:
For laparoscopic assisted vaginal hysterectomy.

The Endoscopic Hysterectomy instrument set consisting of vaginal tube, mandrin and instrumentation insert is used to support LAVH (laparoscopically assisted vaginal hysterectomy).

- The tube is used for visualization of the cervical portio.
  The distal section of the vaginal tube can be seen during laparoscopically assisted vaginal hysterectomy, and thus serves the surgeon as a guide and support during cutting. The tube allows pneumoperitoneum to be maintained during cutting and opening of the posterior vaginal vault.
- The mandrin supports the introduction of the tube into the vagina. Prior to introduction it is inserted into the vaginal tube and locked in place.
- The instrumentation insert has two openings - instrument ports - through which surgical instruments are inserted into the vaginal tube without loss of gas.

Indication: For the use of the uterus manipulator in endoscopic hysterectomy:

- Uterus myomatosis
- Abnormal uterine bleeding

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Nathan /
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964276

Prescription Use ✓ OR Over-The-Counter Use_____
Per CFR 21 CFR 801.109

P2072

Indications for Use:

The Uterus Manipulator set, consisting of uterus manipulator and uterus probe is used to support LAVH.

The uterus manipulator is an instrument with a distally inclinable probe section. The part of the instrument which is inserted in the uterus serves to fix the uterus and change or manipulate its position.

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

Concurrence of CDRH. Office of Device Evaluation (ODE)

Robert R Satterwhite /

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K964276

Prescription Use ✓ OR Over-The-Counter Use____

Per CFR 21 CFR 801.109