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SEP 15 1997

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: March 14, 1997
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: Auxiliary Instruments for URS		Model numbers: See section 1: 'Submitted Devices: Auxiliary Instruments for URS'	
Common name: Rigid and flexible forceps, stone extractors, electrodes, bougies		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 pre-enact.	1 various instruments for urological endoscopes, see equivalent devices	1 Richard Wolf M.I.C.
2	2 various instruments for urological endoscopes, see equivalent devices	2 Circon
3	3 various instruments for urological endoscopes, see equivalent devices	3 Karl Storz
4	4	4

1.0 Description

The submitted auxiliary instruments for URS are accessories for the ureterrenoscopy. These are rigid or flexible biopsy, grasping, and foreign body forceps, stone extractors, unipolar electrodes for high frequency applications, and bougies.

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2.0 Intended Use

The auxiliary instruments for ureteroscopes and uretero-renoscopes are used for preliminary procedures in the ureter and kidney, as well as for procedures in the urethra and bladder.

Flexible and rigid auxiliary instruments can be used in connection with single or double instrument ports.

Various diagnostic and therapeutic procedures can be performed, for example:

- transurethral extraction of uretero calculi
- biopsy for tumor diagnostics
- removal of foreign bodies, e.g. ureteral stents

The interventions are carried out by trained and experienced surgeons who consider the general condition and the anatomic specialties of the patient in their diagnosis.

- The forceps are used for endoscopically controlled grasping, and obtaining tissue specimens for diagnosis. Both flexible and rigid forceps are available.
- The stone extractors (graspers) are used to grasp stones or stone calculi and extract them out of urological tract. The stone extractor is also used to immobilize the calculus while disintegrating the stone.
- Various electrodes are used for controlling bleedings and for removing or destruction of tissue by use of unipolar high-frequency current under endoscopic view.
- The bougies (dilators) are used for the atraumatic distention of tubular organs. The flexible hollow dilators can be inserted over a guide wire, for example into the renal pelvis.

3.0 Technological Characteristics

The basic design of the submitted instruments is similar to the devices sold prior to 1976 and to competitor's products. The diameter of the submitted forceps is smaller; the mouth of the jaws is designed shorter to ensure the same stability.
The submitted forceps, stone extractors, and HF electrodes are adapted to the anatomy in ureterorenoscopy, the working length becomes smaller and longer.

4.0 Substantial Equivalence

These devices are substantially equivalent to existing pre-enactment devices sold by Richard Wolf and 510(k) devices sold by Storz and Circon.

5.0 Performance Data

- Mechanical load test of the forceps and stone graspers show that there is no breakage of the jaw or other parts of the instrument if used normally.
- The steam sterilization in clinical use and tests performed by Richard Wolf show that the steam sterilization has no influence on the functional performance of the submitted instruments when using the fractional method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1997

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

Re: K971315
Auxiliary Instruments for Ureteroscopes
and Uretero-Renoscope (URS)
Dated: July 1, 1997
Received: July 2, 1997
Regulatory Class: II
21 CFR §876.4300, 876.1075, 876.1500, 876.5520,
and 876.4680
Product Code: 78 FAS, FCL, KOG, FAX, and FFL

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,

William Yin

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

INDICATIONS FOR USE

510(k) Number (if known): K971315 Pg 1 of 2

Device Name: Auxiliary Instruments for Ureteroscopes and Uretero-Renoscopes

Indications for Use:

General: The auxiliary instruments for ureteroscopes and uretero-renoscopes are used for preliminary procedures in the ureter and kidney, as well as for procedures in the urethra and bladder.

Flexible and rigid auxiliary instruments can be used in connection with single or double instrument ports.

Various diagnostic and therapeutic procedures can be performed, for example:

- transurethral extraction of uretero calculi
- biopsy for tumor diagnostics
- removal of foreign bodies, e.g. ureteral stents

The interventions are carried out by trained and experienced surgeons who consider the general condition and the anatomic specialties of the patient in their diagnosis.

Forceps: The forceps are used for endoscopically controlled grasping and obtaining tissue specimens for diagnosis. Both flexible and rigid forceps are available.

Stone Extractors: The stone extractors (graspers) are used to grasp stones or stone calculi and extract them out of urological tract. The stone extractor is also used to immobilize the calculus while disintegrating the stone.

The stone extractors are intended for minimally invasive, diagnostic and therapeutic interventions. They are used e.g. in conjunction with ureteroscopes and uretero-renoscopes.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Robert P. Gatting

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971315

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

Electrodes: Various electrodes are used for controlling bleeding and for removing or destruction of tissue by use of unipolar high-frequency current under endoscopic view.

Bougies (Dilators): The bougies are used for the atraumatic distention of tubular organs. The flexible hollow dilators can be inserted over a guide wire, for example into the renal pelvis.

The bougies are intended for minimally invasive, diagnostic and therapeutic interventions.

Contraindications: Contraindications resulting from the general findings or described in the relevant literature must be observed.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971315

Prescription Use ✓ OR Over-The Counter__
Per 21 CFR 801.109