3/26/99

K990050

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Vernon Hills, Illinois 60061
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RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			**Date of Preparation:** January 5, 1999
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: Compact Operating Uretero-Renoscope by Gautier		**Model number:** 8706.402 / .042	
Common name: Uretero-Renoscopes		**Classification name:** Ureteroscopes	
Information on devices to which substantial equivalence is claimed:			

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K963855	1 Uretero-renoscope	1 Richard Wolf
2	2	2

1.0 Description

Uretero-rensoscope 8706.402 is a thin endoscope with a rod lens system, a channel for irrigation and for the simultaneous use of an instrument.

The uretero-renoscope may be inserted with the introduction sheath, 8706.042 to view the renal pelvis. The introduction sheath remains stationary while the uretero-renoscope may be removed and replaced by a flexible uretero-renoscope when reaching the upper calyx group.

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2.0 Intended Use

The compact operating Uretero-Renoscope 8706.402 is used to examine the ureter and kidney. Various diagnostic and therapeutic procedures can be performed by using additional accessories.

The insertion sleeve, 8706.042 is used as a guide during insertion of the flexible uretero-renoscope and for evacuation of irrigation solution.

3.0 Technological Characteristics

- atraumatic tip for problem free introduction into the uteri ostium
- sharp, brilliant quality over the entire image
- autoclavable / steam sterilization 134°C / 273°C

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing devices sold by Richard Wolf.

5.0 Performance Data

No performance standards are known.

6.0 Clinical Tests

Clinical tests performed were not performed.

7.0 Conclusions Drawn

These devices are designed and tested to assure their safety and effectiveness when used according to the instructions manual.

By: Robert L. Casarsa Date: Jan 4 99

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 1999

Mr. Robert L. Casarsa
Quality Assurance Manager
RICHARD WOLF Medical Instruments Corp.
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K990050
Compact Operating Uretero-Renoscope
with Insertion Sleeve
Dated: January 5, 1999
Received: January 7, 1999
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FGB

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 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. 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 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, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): K 990050

Device Name: Compact Operating Uretero-Renoscope with Insertion Sleeve

Intended Use:

The compact operating Uretero-Renoscope 8706.402 is used to examine the ureter and kidney. Various diagnostic and therapeutic procedures can be performed by using additional accessories.

- transurethral extraction and lithotripsy of ureteroliths and kidney stones via electrohydraulic, laser, pneumatic, or ultrasonic technology.
- tumor diagnostics and / or biopsy
- removal of foreign bodies

The insertion sleeve, 8706.042 is used as a guide during insertion of the flexible uretero-renoscope and for evacuation of irrigation solution.

Contraindications:

For all submitted ureteroscopes and ureter-renoscopes:
Comply with contraindications for the patient which result from general findings and are described in relevant literature, for example:

- acute hypertrophy of the prostate
- stenosis of the ureter

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990050

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