

JUN - 5 2000

K 994223

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

RICHARD WOLF
 MEDICAL INSTRUMENTS CORPORATION



510(k) Summary of Safety and Effectiveness

| | | | |
|--|--|--|------------------------------------|
| 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: Nephroscope Set | | Model number: 8964.xxx, 8965.xxx | |
| Common name: Nephroscope Set | | 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-enactment | 1 Fiber Kight Operating Laparoscope 4937 | 1 Richard Wolf | |
| 2 K770729 | 2 Pylescope System | 2 Richard Wolf | |
| 3 | 3 Operating Syet for Percutaneous Removal of Kidney Stones 27090 / 27092 / 27093 | 3 Karl Stoz | |
| 4 | 4 Rigid Percutaneous Nephroscope MRO-20 | 4 Circon ACMI | |

1.0 Description

The universal nephroscope has a reduced sheath diameter and an expanded working channel to accommodate auxiliary instruments and irrigation. The submitted nephroscope design has been modified to optimize user handling.

2.0 Intended Use

The nephroscope, with its accessories, is used, with suction, for the disintegration and removal / extraction of kidney and bladder stones. The stones are removed, under endoscopic control, through percutaneous or transurethral passages, in conjunction with intercorporeal pneumatic, ultrasound, electrohydraulic or laser lithotriptors.



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3.0 Technological Characteristics

The submitted nephroscope can be held by the elongated right angled light connected which has been designed with a recessed grip and a thumb ring. An automatic valve for instrument insertion and an automatic locking mechanism between the endoscope and sheath is part of the submitted design. Accessory instruments have been adapted to the longer nephroscope.

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 510(k) devices sold by Richard Wolf, Karl Storz, and Circon ACMI.

5.0 Performance Data

No known performance standards.

The devices conform to international standards IEC 601-1 and IEC 601-2-18 and to the relevant provisions of the European Device Directive 93/42/EEC. The EC Certification is pending.

6.0 Clinical Tests

Clinical tests 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
Robert L. Casarsa
Quality Assurance Manager

Date: Dec 10, 1999



JUN - 5 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994223
Nephroscope and Accessories
Dated: April 7, 2000
Received: April 10, 2000
Regulatory Class: II
21 CFR §876.1500/Procode: 78 FGA, FEC and FED
Regulatory Class: II Exempt
21 CFR §876.4680/Procode: 78 FFL

Dear Mr. Casarsa:

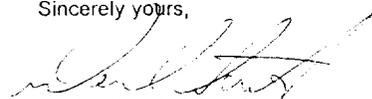
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4591. 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" (21CFR 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,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Indications of Use

510(k) Number (if known): K 994223

Device Name: Endoscopes

Intended Use:

The nephroscope, with its accessories, is used, with suction, for the disintegration and removal / extraction of kidney and bladder stones. The stones are removed, under endoscopic control, through percutaneous or transurethral passages, in conjunction with intercorporeal pneumatic, ultrasound, electrohydraulic or laser lithotriptors.

Indications and Fields of Application:

For diagnosis and therapy with endoscopic accessories in the upper and lower urogenital tract when performed by trained and qualified medical personnel.

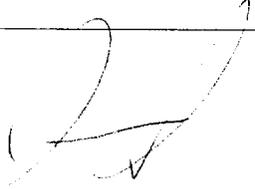
Contraindications:

Contraindications directly related to the product are presently unknown. The attending physician must determine if the planned application is appropriate based on the patient's general condition. Refer to current technical literature for further instructions.

Combinations:

The nephroscope is used in connection with intracorporeal lithotripsy systems, e.g. ultrasound, EHL, etc., suction and irrigation devices, light sources and flexible light cables, video cameras and objective lenses as well as endoscopies accessories, e.g., grasping forceps, stone extractors, stricture scalpel.

(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 K994223

Prescription Use
Per 21 CFR 801.109

OR
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Over-The Counter _____