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K980401

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

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MAY 21 1998

510(k) Summary of Safety and Effectiveness

Submitter:	**Date of Preparation:** May 1, 1998
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:	State/Province:	Country:	ZIP / Postal Code:
Vernon Hills	Illinois	USA	60061

Contact name: Mr. Robert L. Casarsa

Contact title: Quality Assurance Manager

Product Information:

Trade name: Flexible fiberscopes and accessories	**Model number:** 7305.xxx
Common name: Flexible fiberscopes	**Classification name:** Flexible endoscopes

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K962172	1 Flexible Mini-Fiberscopes	1 Richard Wolf
2	2 Flexible CystoNephroscope ACN	2 Circon/ ACMI
3	3 Flexible Hysteroscope, AUR-FH	3 Circon/ACMI
4	4 Cysto-Urethro-Fiberscope 11272 AA	4 Karl Storz
5	5 Flexible Hysteroscope, 11261 BB	5 Karl Storz
6	6 Flexible Cystofiberscope CYF-3	6 Olympus
7	7 Hysterofiberscope, HYF-1T	7 Olympus

1.0 Description

The flexible fiberscopes consist of a flexible insertion part, a control part and an eyepiece for direct view or connection to a video camera.

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2.0 Intended Use

Flexible fiberscopes are used for examination, diagnosis, and/or therapy in connection with endoscopic accessories and auxiliary instruments used through the working channel of the instrument for use in urology, surgery, and OB/GYN.

3.0 Technological Characteristics

There are no significant technological changes or characteristics to the new devices compared to the existing devices.

The tip of the sheath has an active deflection up to 360°, depending on the fiberscope. The deflecting position can be locked with a brake at the 7305.001. The image is transmitted via objective, fiber bundle and eyepiece for direct view or connection to a video camera. The total number of pixels and the fibers per mm^2 are increased to get an image with higher resolution. Biopsy material can be taken by the wide working channel, which is simultaneously used for irrigation. Auxiliary instruments such as grasping forceps, stone extractors or HF button electrode are inserted via a proximal mounted insertion cock with supply and discharge. A leakage test unit or a gas sterilization valve can be connected to an attachment of the fiberscope.

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 pre-enactment and 510(k) devices sold by Richard Wolf in the urology branch. In addition, the submitted devices are substantially equivalent to devices sold by Circon, Karl Storz and Olympus.

5.0 Performance Data

No known FDA performance standard exists.

The electrodes in combination with the fiberscopes were tested to meet the appropriate sections of the ANSI/ AAMI standard on high frequency devices HF18 and IEC601-1/ IEC601-2-2.

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:** May 1, 1998

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAY 21 1998

Re: K980401
Flexible Fiberscopes and Accessories
Dated: May 1, 1998
Received: May 4, 1998
Regulatory Class: II
21 CFR §876.1500 and §884.1690
Product Code: 78 FAJ GCJ, and 84 HIH

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 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,

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): K980401

Device Name: Flexible Fiberscopes and Accessories (7305.001, 7305.011)

Intended Use:

For examination, diagnosis and/or therapy in connection with endoscopic accessories and auxiliary instruments used through the working channel of the instrument for use in urology, surgery, and GYN.

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

Robert R Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980401

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter