DEC 2 1998

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

K983279

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: September 16, 1998
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation 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: 1 CCD Endocam, Electronic CCD Endoscope	Model number: 5502, 4934
Common name: Endoscopic Video Camera System	Classification Name: Endoscope and / or Accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K950502	1 CCD Endocam	1 Richard Wolf M.I.C.
2 K942817	2 CCD Endocam Office	2 Richard Wolf M.I.C.
3	3	3
4	4	4
5	5	5
6	6	6

1.0 Description

The electronic CCD Endoscope is a combination of an endoscope with integrated objective lenses and CCD camera. The CCD endoscope is connected to the camera controller 5502 via a quick connector with camera cable.

2.0 Intended Use

The 1CCD Endocam 5502 is designed for video endoscopy and video microscopy. It can be used for both diagnostic and therapeutic interventions. The Electronic CCD Endoscopes are used for viewing the inside of the patient via natural or surgically created passages.

3.0 Technological Characteristics

The electronic CCD Endoscope has a CCD image converter with color mosaic filter. The light falls through the integrated lenses onto the sensor which generates a signal. The signal is processed in the camera controller to a standard NTSC video signal.

The electronic CCD Endoscope is insulated from earth (type BF-Equipment, according to UL2601-1 / IEC601-1.)

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as existing 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.

5.0 Performance Data

Independent laboratories tested Endocam 5502 and 5507 according to specified standard IEC601-1, IEC601-1-2, IEC1-1-2, IEC1-2-18 and UL2601-1, and AAMI safe current limits.

Camera system 5502 conforms to the relevant provisions of Medical Device Directive 93/42/EEC

6.0 Clinical Tests

No clinical tests performed.

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 J. Casarsa Date: Sept 14, 98

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1998

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

Re: K983279
Trade Name: 1 CCD Multi-Endocam 5502 with Electronic CCD Endoscope
Regulatory Class: II
Product Code: GCJ
Dated: September 16, 1998
Received: September 18, 1998

Dear Mr. Casarsa:

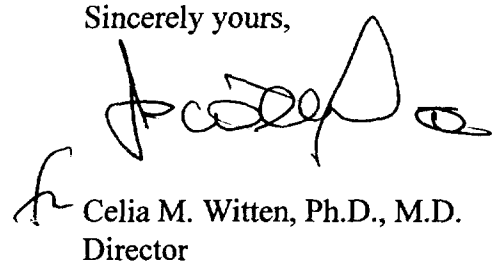
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K983279

Device Name: 1 CCD Multi-Endocam 5502 with Electronic CCD Endoscope

Intended Use:

The 1CCD Endocam 5502 is designed for video endoscopy and video microscopy. It can be used for both diagnostic and therapeutic interventions. The Electronic CCD Endoscopes are used for viewing the inside of the patient via natural or surgically created passages.

Indication and Field of Application:

For use in various medical disciplines, such as urology, thorax surgery, gastroenterology, by adequately trained and qualified personnel.

Contraindications:

Inflammations or bacterial contamination of wounds in the operating area. Contradindications related directly to the product are currently unknown. The attending physician must determine if the intended application is appropriate. For additional information, refer to the latest specialized medical literature.

Combinations:

Electronic CCD endoscopes are used in connection with the 1 CCD Endocam 5502 and light sources with flexible light cables, as well as, endoscopic accessories, e.g. trocar sleeves.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983279

Prescription Use X
Per 21 CRF 801.109

OR

Over-The Counter