NOV 23 1998

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K982965

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: August 24, 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 and 3 CCD Endocam	Model number: 5502 and 5507
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 endoscopic video camera systems include a camera controller and a small camera head which is connected by a camera cable to the controller. Endoscopic procedures are displayed with the objective lenses attached to the camera head and the video monitors connected to the camera controller.

The camera heads are CF Equipment (cardiac floating) according to UL2601-1 / IEC601-1.

2.0 Intended Use

The 1 CCD Endocam 5502 and 3 CCD Endocam 5507 are designed for video endoscopy and video microscopy and can be used for both diagnostic and therapeutic interventions.

The camera head is classified as Cardiac Floating (CF) equipment with less than 10µA of leakage current. This permits its use for cardiac visualization procedures when used in conjuction with the proper instrumentation for entry into the cardiac system.

3.0 Technological Characteristics

The 1 CCD Endocam 5502 has a CCD image converter with mosaic color filter.

The 3 CCD Endocam 5507 has three CCD image converter for red, green and blue colors, separated by a prism. The light that falls onto the sensor generates a signal which is processed in the camera controller to a standard NTSC video signal.

The camera head is insulated from earth (Type CF-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 (5507: UL pending).

Camera systems 5502 and 5507 conform 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 L. Casarsa Date: 9-4-98

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 1998

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

Re: K982965
Trade Name: 1 CCD Endocam 5502 and 3 CCD Endocam 5507 with CF Camera Heads
Regulatory Class: II
Product Code: FWF
Dated: August 24, 1998
Received: August 25, 1998

Dear Mr. Casarsa:

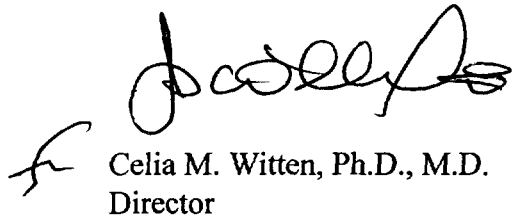
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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): K982965

Device Name: 1 CCD Endocam 5502 and 3 CCD Endocam 5507 with CF Camera Heads

Intended Use:

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(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 K982965

Prescription Use X
Per 21 CFR 801.109

OR

Over-The Counter