

NOV 24 1997

L973359

RICHARD WOLF
 MEDICAL INSTRUMENTS CORPORATION



510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: September 4, 1997	
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: PANOVIEW PLUS telescopes 3.5 mm		Model number: 8379.401, .402, .403	
Common name: MINI Laparoscopes		Classification name: Laparoscopes	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 pre-enactment	1 Lumina Telescope	1 Richard Wolf	
2	2 Pediatric Laparoscopes	2 Karl Storz	
3	3 Laparoscopes	3 Jarit	
4	4	4	

1.0 Description

The PANOVIEW PLUS telescopes are part of the MICRO and MINI instrument set for laparoscopic microsurgery. They are particularly suitable for diagnostics, smaller interventions, and outpatient and pediatric laparoscopy.

2.0 Intended Use

The MINI laparoscopes provide visualization inside the patient by natural or surgically generated access.

3.0 Technological Characteristics

The endoscopes design and biocompatibility of materials is comparable to earlier Richard Wolf devices. The outer diameter of the submitted devices are smaller and provide minimally invasive laparoscopy. The smaller diameter of the lens results in a smaller endoscopic puncture.

4.0 Substantial Equivalence

The devices are substantially equivalent to existing pre-enactment devices and 510(k) devices sold by Richard Wolf, Karl Storz, and Jarit.

5.0 Performance Data

No know FDA performance standards exist.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

The devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manual.

By: _____

Robert L. Casarsa

Robert L. Casarsa
Quality Assurance Manager

Date: _____

Sept 3, 97



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, Illinois 60061

NOV 24 1997

Re: K973359
Trade Name: Mini Laparoscopes/PanoView PLUS telescopes 3.5
Regulatory Class: II
Product Code: GCJ
Dated: September 4, 1997
Received: September 8, 1997

Dear Mr. Casarsa:

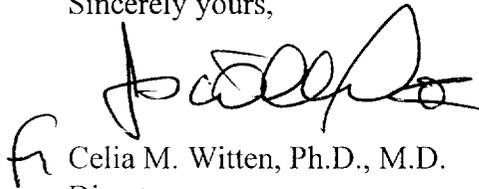
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', is written over a large, faint, stylized letter 'f'.

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): 973359

Device Name: PANOVIEV PLUS telescope, 3.5 mm

Intended Use:

The MINI Laparoscopes provide visualization inside the patient via natural or surgical generated access.

Indication:

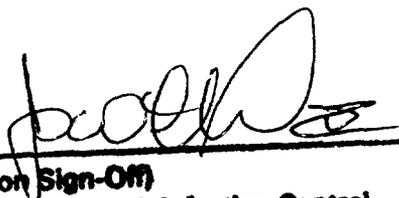
For examination, diagnostics, and/or therapy for use by surgeons who are trained and qualified in the use of endoscopically used accessories from various medical specialties, such as surgery, urology, gynecology, and ENT.

Contraindications:

There are no know contraindications directly related to the product. The attending physician must consider the general condition of the patient when determining if the application is appropriate.

Combinations:

The endoscopes are used in connection with light sources and flexible light cables, video cameras or reflex cameras and objective lenses, as well as accessories for endoscopic use, e.g., trocar sleeves, forceps, electrodes.



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973359

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use X
Per 21 CFR 801.109

OR

Over-The Counter