

NOV - 6 1997

RICHARD WOLF
 MEDICAL INSTRUMENTS CORPORATION



K972927

510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: August 5, 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 Telescopes		Model number: 8880.401, 8880.431, 8880.402, 8880.403, 8933.441, 8933.401, 8933.442, 8933.402, 8933.441, 8933.421, 8934.442, 8934.422	
Common name: Endoscopes		Classification name: Laparoscope, Plastic and General Surgery	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 K951519	1 WECO Endoscopic System w/ Fiber Optic Light	1 Wells Endoscopic Company	
2	2 Endoscope	2 Storz	
3	3 EndoPlastic™ Scope, 10mm	3 Snowden-Pencer	
4 K960400	4 Diamond-View™ Non-Autoclavable Endoscopes, 10mm	4 Snowden-Pencer	
5	5	5	

1.0 Description

The Richard Wolf Endoscopes have 4mm, 7mm, and 10mm diameters with working lengths ranging from 190mm to 300 mm. They have a viewing direction of 0°, 25°, and 50°. The eyepieces are fixed or detachable, depending upon the specific model.



Revised 10/97

2.0 Intended Use

Richard Wolf endoscopes for use in plastic surgery are designed to visualize anatomy through natural and man-made openings in body cavities. The endoscopes may be used to visualize subcutaneous tissue when the indicated application is endoscopic cosmetic surgery of the facial and forehead, breast augmentation, and endoscopic abdominalplasty procedures.

3.0 Technological Characteristics

- Removable and permanent eyepiece

4.0 Substantial Equivalence

The Richard Wolf Endoscopes for plastic surgery are substantially equivalent to:

- Snowden-Pencer
- Wells Endoscopy
- Karl Storz
- Storz (USA)

All devices have the same intended use.

5.0 Performance Data

6.0 Clinical Tests

None

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*
Robert L. Casarsa
Quality Assurance Manager

Date: *Aug 5, 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 - 6 1997

Re: K972927
Trade Name: Panoview Telescopes
Regulatory Class: II
Product Code: GCJ
Dated: August 5, 1997
Received: August 8, 1997

Dear Mr. Casarsa:

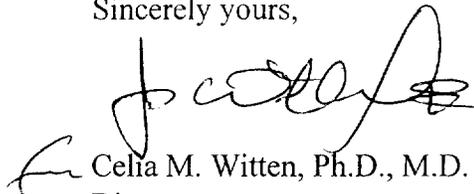
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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. Failure to comply with the GMP regulation may result in regulatory action. 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 the typed name.

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

510(k) Number (if known): K972927

Device Name: Endoscopes for Plastic Surgery

Indications for Use:

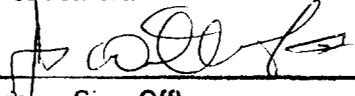
Indications for Use:

Richard Wolf endoscopes for use in plastic surgery, are designed to visualize anatomy through natural and man-made openings in body cavities. The endoscope(s) may be used to visualize subcutaneous tissue when the indicated application is endoscopic plastic/reconstructive surgery.

Revised 10/31/97

(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 K972927

Prescription Use X
Per CFR 21 CFR 801.109

OR

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Over-The-Counter Use _____