

AUG 12 1999

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 Vernon Hills, Illinois 60061  
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**RICHARD WOLF**  
 MEDICAL INSTRUMENTS CORPORATION



K991718

**510(k) Summary of Safety and Effectiveness**

<b>Submitter:</b>		<b>Date of Preparation:</b> May 18, 1999	
Company / Institution name: <b>RICHARD WOLF MEDICAL INSTRUMENTS CORP.</b>		FDA establishment registration number: 1418479	
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			
<b>Product Information:</b>			
Trade name: Operating Laparoscopes		Model number: 8912.402, 8914.402, 8915.402 and accessories	
Common name: Laparoscopes with working channel		Classification name: Laparoscopes	
<b>Information on devices to which substantial equivalence is claimed:</b>			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 pre-enact.	1 Operating Peritoneoscope 4937	1 Richard Wolf	
2	2	2	

**1.0 Description**

The operating laparoscopes are endoscopes with working channels. The optic of the endoscopes is distortion-free. The instrument ports with automatic valves or insertion cocks are detachable and can be replaced by a laser coupler. The submitted laparoscopes are steam-sterilizable.



**2.0 Intended Use**

The operating laparoscopes are used for viewing the interior of the patient through surgically produced accesses; for examination, diagnosis and / or therapy in connection with endoscopic accessories for laparoscopy.

**3.0 Technological Characteristics**

- distortion free
- autoclavable 134°C / 273°F
- detachable instrument port with insertion cock
- detachable laser coupler for CO<sub>2</sub> laser

**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 devices sold by Richard Wolf.

**5.0 Performance Data**

The devices conform to IEC 601-1 and IEC 601-2-18, and to the relevant provisions of European 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 instructions manual.

By:   
Robert L. Casarsa  
Quality Assurance Manager

Date: May 18, 99



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 12 1999

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

Re: K991718  
Trade Name: Laparoscopes Models 8912.402, 8914.402, and 8915.402  
Regulatory Class: II  
Product Code: GCJ  
Dated: May 18, 1999  
Received: May 20, 1999

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.

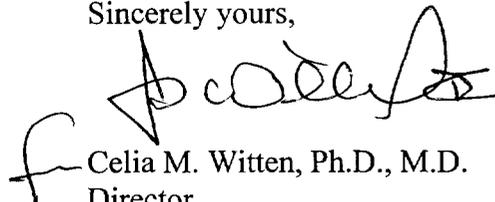
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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 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.

Page 2 – Mr. Robert L. Casarsa

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 legally marketed predicate devices 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". The signature is written in a cursive style with a large initial "C" and "W".

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):     K991718    

Device Name:     Operating Laparoscopes    

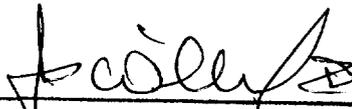
**Intended Use:**

The operating laparoscopes are used for viewing the interior of the patient through surgically produced accesses; for examination, diagnosis and / or therapy in connection with endoscopic accessories for laparoscopy.

**Combinations:**

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

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



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number     K991718    

Prescription Use     X      
Per 21 CFR 801.109

OR

Over-The Counter