

AUG 27 1997

K971166

<b>510(k) Summary of Safety and Effectiveness</b>			
<b>Submitter:</b>		Date of Preparation: March 28, 1997	
Company / Institution name: <b>RICHARD WOLF MEDICAL INSTRUMENTS CORP.</b>		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			
<b>Product Information:</b>			
Trade name: Optical Mediastinoscope and Accessories		Model number: 8783.401, 8783.411 and accessories (see section I: Submitted devices)	
Common name: Mediastinoscope		Classification name: Mediastinoscope and Accessories	
<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 Fiber Light Mediastinoscope 8960.01/ .03	1 Richard Wolf M.I.C.	
2 K 95 49 10	2 Optical Mediastinoscope 10970BV	2 Karl Storz	
3	3 Mediastinoscope 'CARLENS' 10970A/B and operating instruments	3 Karl Storz	

**1.0 Description**

The Optical Mediastinoscope is a tubular, conical shaped endoscope with a handle and a build-in telescope with fiber illumination which is bent at a 90° angle. The endoscope tube consists of two spreadable spatulas which allow distention of the operative field, and therefore, optimizes vision. The spatulas may be dismounted for easier cleaning.

For efficiency during diagnostic and therapeutic procedures, a variety of accessory instruments are needed, e.g. biopsy and grasping forceps, puncture, suction and coagulation tubes or telescope rinsing tubes.

## **2.0 Intended Use**

The Mediastinoscope, in connection with various auxiliary instruments, is used for diagnostic and/or surgical interventions in the upper area of the mediastinum.

Various auxiliary instruments are used in mediastinoscopy:

- The smoke evacuation tube is used to evacuate smoke during HF or laser applications.
- The telescope rinsing tube (optic irrigation tube) is used to keep the distal part of the telescope clear by rinsing with irrigation fluid.
- The mediastinal puncture tube is used to puncture lymph nodules and aspirate the content for cyto/hystological purposes.
- The tumor grasping forceps are used for grasping and manipulating tissue.
- The micro grasping forceps with HF are used for coagulating small vessels and grasping.
- The HF coagulation suction devices are used for suction and for coagulation while holding tissue 'out of the way' during endoscopic operations of the larynx in connection with CO<sub>2</sub> lasers or in mediastinoscopy.
- The bipolar coagulation suction tube (bipolar aspiration tube) is used for aspiration and for coagulation of small lesions.

## **3.0 Technological Characteristics**

- 90° bent telescope, diameter of lens 2.78 mm
- direction of view 35°, angle of view 98°
- spreadable spatula, consisting of two half pieces, wall thickness 1 mm
- spatula diameter: distal ca. 17 mm, proximal 28 x 18.5 mm
- working length 160 mm

## **4.0 Substantial Equivalence**

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

## **5.0 Performance Data**

- Pull tests of the optical mediastinoscope show that there is no permanent deformation if used normally.
- Mechanical load tests of the forceps and stone extractors show that there is no breakage of the jaw or other parts if used normally.
- Steam sterilization in clinical use and tests performed by Richard Wolf show that the steam sterilization has no influence on the functional performance of the submitted devices when using the fractional method.

## **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  
Robert L. Casarsa  
Quality Assurance Manager

Date: July 14, 1997



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K971166  
Trade Name: Optical Mediastinoscope and Accessories  
Regulatory Class: II  
Product Code: EWY  
Dated: June 14, 1997  
Received: July 16, 1997

AUG 27 1997

Dear Mr. Casarsa:

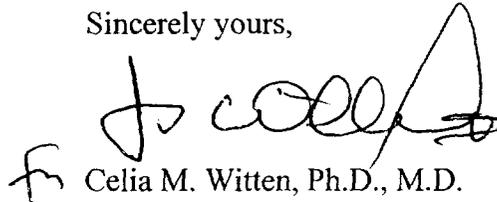
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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". The signature is stylized 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): K971166

Device Name: Mediastinoscope and Auxiliary Instruments

## Indications for Use:

The Mediastinoscope, in connection with various auxiliary instruments, is used for diagnostic and/or surgical interventions in the upper area of the mediastinum.

Mediastinoscopy is carried out:

- In order to evaluate the operability of patients suffering from bronchial carcinoma which have already been verified, for treatment planning of other carcinomas in the mediastinal area and for biopsies.
- For diagnostic clarification of primary and secondary diseases of the mediastinum, when other examination methods have been unable to provide the nature, and in particular the histological character of the disturbance.
- For the removal of nodes and tumors.
- For the diagnosis and removal of lymphatic nodes.

*revised 7/14/97*

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Concurrence of CDRH Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K971166

Prescription Use   
Per 21 CFR 801.109

OR

Over-The Counter \_\_\_\_\_

**Indications Continued:**

Various auxiliary instruments are used in mediastinoscopy:

- The smoke evacuation tube is used to evacuate smoke during HF or laser applications.
- The telescope rinsing tube (optic irrigation tube) is used to keep the distal area of the telescope clear by rinsing with irrigation fluid.
- The mediastinal puncture tube is used to puncture lymph nodules and aspirate the content for cyto/histological purposes.
- The tumor grasping forceps are used for grasping and manipulating tissue.
- The micro grasping forceps with HF are used for coagulating small vessels and grasping.
- The HF coagulation suction devices are used for suction and for coagulation while holding tissue 'out of the way' during endoscopic operations of the larynx in connection with CO<sub>2</sub> lasers or in mediastinoscopy.
- The bipolar aspiration tube (bipolar coagulation suction tube) is used for aspiration and for coagulation of small lesions.

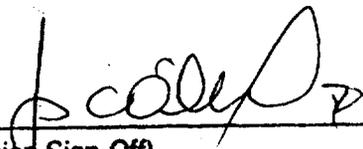
**Contraindications:**

Contraindications for the patient which result from the general findings are described in the relevant literature and must be observed.

*Revised 7/14/97*

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