

APR - 3 1997

353 Corporate Woods Parkway  
Vernon Hills, Illinois 60061  
Telephone: 847.913.1113  
Fax: 847.913.1488

## 510(k) Summary of Safety and Effectiveness

K963855

<b>Submitter:</b>		<b>Date of Preparation:</b> August 23, 1996	
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: Compact Operating Fiber Uretero-Renoscopes and Ureterscopes		Model number: 8712.402, 8702.402, 8703.402, 8707.402, 8705.402, 8719.401, 8708.401, 8718.401, 8708.403, 8718.403, 8714.401, 8704.401 and accessories: 8952.313, 8954.765, 8954.766, 8708.253	
Common name: Ureterscopes		Classification name: Endoscope 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 Cysto-Urethroscope 4616	1 Richard Wolf M.I.C.	
2 pre-enact.	2 Cysto-Urethroscope 8616.10	2 Richard Wolf M.I.C.	
3 K 94 04 64	3 Slender Uretero-Renoscope 27023AS	3 Storz	
4	4 Ureterscopes Micro-6 / Micro-6 long	4 Circon	
5 K 94 04 64	5 Operating Uretero-Renoscope 27024KE/KB	5 Storz	
6	6 Operating Ureterscopes MR-7 Series	6 Circon	

**1.0 Description**

The submitted devices are thin endoscopes with fiber image bundle and an oval channel for irrigation and for use of one or two instruments simultaneously.

The devices have a direct view, an oblique or an offset eyepiece.

A single or double instrument port is needed for the insertion of the auxiliary instruments. For lithoclast application an additional guide is used.

The longer endoscopes are called uretero-renoscopes and are used for procedures in ureter and kidney. The shorter ones are called ureterscopes and are used for procedures in ureter (and for procedures in kidney, if the urinary tract is short enough).

**2.0 Intended Use**

The submitted ureteroscopes and uretero-renoscopes are used to examine the ureter and kidney. Various diagnostic and therapeutic procedures can be performed by using additional accessories, for example disintegration of ureteroliths and kidney stones, biopsy for tumor diagnosis or removal of foreign bodies.

**3.0 Technological Characteristics**

- autoclavable (steam sterilization) for high hygiene demands
- high resolution image bundle with reduced pixel size, down to 30,000 pixels for realistic reproduction of the operation site (8702.402 and 8712.402 14,000 pixels)
- atraumatic tip for problem free introduction into the uteric ostium
- bright wide angle telescope and high flow rate for optimal visualization

**4.0 Substantial Equivalence**

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

**5.0 Performance Data**

Mechanical load test (bending test) shows, that there is no fracture of the shaft if normally used. The steam sterilization in the clinical use and the tests performed by Richard Wolf shows, that the steam sterilization has no influence to the optical quality of the Uretero-Renoscopes, 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: Jan 17, 97