JUL 20 1998

K980302

P1 of 3

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

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness			
Submitter:		**Date of Preparation:** January 23, 1998	
Company / Institution Name: **Richard Wolf Medical Instruments Corporation**		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 Casarsa			
Contact Title: Quality Assurance Manager			
Product Information			
Trade Name: Resectoscopes E-Line		Model Number: 8654, 8655, 8656, 8657, 8658, 8661, 8663, 8666, 8668, 8407 to 8439	
Common Name: Resectoscope		Classification Name: Resectoscope, Resectoscope, Working Element	

Information on devices to which substantial equivalence is claimed:		
510(k) Number	Trade or proprietary or model name	Manufacturer
1 K895857/A	1 Continuous Irrigation Resectoscope System, Model 8655	1 Richard Wolf
2 K953983	2 EVAP Electrodes Model 8423, 8427, 8410, 8413	2 Richard Wolf
3	3 USA Elite System Resectoscopes	3 Circon ACMI
4	4 Resectoscopes 27040-27050, 27143	4 Karl Storz

K980302
p2 of 2

1.0 Description

The **resectoscopes** consist of working elements, standard and continuous-irrigation resectoscope sheaths, coagulation and cutting electrodes, standard, timerlake (deflecting) and visual obturators, and endoscopes. The working element is the carrier of the endoscope and guide element to the electrodes.

The **standard resectoscope** sheath is inserted together with obturators in to the body opening to enable an atraumatic passage. After removal of the obturators, the shaft provides a guidance for the working element and rinsing charge or discharge, while the distal sheath simultaneously serves as a cutting-edge.

The **obturator** fills the hollow sheaths. The visual obturator in combination with the endoscope is used to insert the sheath under vision. The standard electrodes are used for combined cutting and coagulation of soft tissue, e.g. prostate or myoma.

The inside of the patient is visualized when the **endoscope** is inserted into the body through natural or surgically generated access.

2.0 Intended Use

Resectoscopes are used for endoscopically controlled ablation of tissue.

Indication: For the examination, diagnosis and/ or therapy in combination with endoscopic accessories in the various medical disciplines, such as, urology, gynecology, and surgery.

Field of Application: TURP (Transurethral Resection of Prostate), TURB (Transurethral Resection of Bladder Tumors), adenomas, myoma resection, soft tissue tumor, endometrium ablation, as well as slitting of the neck of the bladder and incision of the prostate.

Long sheath resectoscopes are used with long urethras.

3.0 Technological Characteristics

The resectoscopes improved design and material achieves a more efficient operation.

The new E-Line working elements have a spring forced reduced by 55% from the earlier generation, while the sliding ability is improved. The resulting operation shows less signs of fatigue.

The material used for the new E-Line resectoscope sheath insulation at the cut-off edge is ceramic rather than GFK which results in higher wear resistance. The submitted sheaths are made from Titan rather than brass / new silver which produces a housing approximately 20% lighter than its predecessor. Some of the continuous irrigation sheaths are oval which improve the flow-off rate.

The submitted E-Line electrode insulation is made from Hytrel instead of Teflon which produces size accuracy and improves sealing.

Improved temperature resistance and processing is achieved by replacing Maranyl with Radel.

K980302
P303

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf, Circon, and Karl Storz.

5.0 Performance Data

No performance standards are known.

The devices conform to the relevant provisions of European Device Directive 93/42/EEC.

Endurance tests and steam sterilization tests were performed to guarantee that the devices are safe and effective.

The HF devices were tested for conformity with the specified standards ANSI/AAMI HF 18, IEC 601-2-2 / IEC 601-2-18.

6.0 Clinical Tests

No clinical tests were performed.

7.0 Conclusions Drawn

The devices were designed and tested to guarantee the safety and effectiveness when used according to the instruction manuals.

By: Robert L. Casarsa Date: Jan 23, 98

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUL 20 1998

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, IL 60061

Re: K980302
Resectoscopes, Instruments and Accessories E-Line
(working elements, standard and continuous irrigation resectoscope sheaths, coagulation and cutting electrodes, and obturators)
Dated: April 21, 1998
Received: April 22, 1998
Regulatory Class: II
21 CFR 884.1690/Procode: 85 HIH
21 CFR 876.1500/Procodes: 78 FJL
78 FDC
78 FAS

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is 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 device, 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 device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device 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 device 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device 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) 594-4613. Additionally, for questions on the promotion and advertising of your device, 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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K980302

Device Name: Resectospes, Instruments and Accessories E-Line, consisting of working channels, standard and continuous irrigation, resectoscope sheaths, coagulation and cutting electrodes, standard, timberlake (deflecting) and visual obturators, and endoscopes

Indications for Use:

Intended Use:

Resectoscopes are used for endoscopically controlled ablation of tissue. They are used, in combination with endoscopic accessories, for examination, diagnosis, and / or therapy in various medical disciplines, such as urology and gynecology.

Revised 7/15/98

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Robert Rathbun

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980302

Prescription Use ✓
Per CRF 21 CFR 801.109

OR

Over-The Counter Use_____