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K973737
P1/2

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

DEC 12 1997

Submitter:			Date of Preparation: September 26, 1997
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation 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: Trocar sleeves and trocars, Dilatation sleeve and guide rod	Model number: 8930.xxx, 8756.xxx, 8309.xxx, 8903.xxx
Common name: Trocar sleeves and trocars	Classification Name: Trocar

Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name		Manufacturer
1 pre-enact.	1 Trocar sleeve with trocar	4940AB	1 Richard Wolf
2 K932441	2 Trocar system	8920.xxx	2 Richard Wolf
3 K942201	3 Laparoscopy dilation system	8934.xxx,...	3 Richard Wolf
4	4 Trocars and thread sleeve		4 Karl Storz
5	5 Trocars/ cannulas systems		5 Jarit

1.0 Description

The trocar sleeves are part of the MICRO and MINI instrument set for laparoscopic microsurgery; particularily suitable for diagnostics, smaller interventions, outpatient, and pediatric laparoscopy.

The instruments smaller diameter allows better cosmetic effects than the larger diameters because they are less invasive.

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2.0 Intended Use

The trocar sleeves and trocars serve to provide artificial access to body cavities.

Trocar sleeves of smaller diameters can be replaced with trocar sleeves of bigger diameters with the dilation set.

3.0 Technological Characteristics

The trocar sleeves and trocars have comparable biocompatible device materials as previous R.Wolf devices. The dimensions are smaller to perform minimally invasive laparoscopy. Partly the trocar sleeves are without automatic valves as a result of minimizing the sealing housing.

4.0 Substantial Equivalence

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

5.0 Performance Data

The steam sterilization 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 Date: Sept 25, 97

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

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

Re: K973737
MINI Trocar sleeve and trocars 3.5 mm; MICRO Trocar sleeve and trocars 2 mm; Dilatation sleeve and guide rod 2 - 3.5 mm
Dated: September 26, 1997
Received: September 30, 1997
Regulatory class: II
21 CFR §884.1720/Product code: 85 HET
21 CFR §876.1500/Product code: 78 FDE

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 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 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/dsmamain.html".

Sincerely yours,

William Yin

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): K973737

Device Name: Trocar sleeves, trocars and dilation sleeve

Intended Use:

The **trocar sleeves** and **trocars** serve to gain access to body cavities.

The **dilation set** is used for enlarging the access; trocar sleeves of smaller diameters can be replaced with trocar sleeves of larger diameters.

Indication and Scope of Application:

For examination, diagnosis, and/or therapy when used in conjunction with endoscopic accessories in the various medical specialties such as surgery, urology and, gynecology when used by suitably trained and qualified specialists.

Contraindications:

There are currently no known contraindications relating directly to the product. The physician should decide whether or not the planned application can be performed based on the of the patient's general condition.

Combinations:

The trocar sleeves and trocars are used in with insufflators, reducing adapters, reducing sleeves, extraction sleeves, dilation sleeves, guide rods, threaded fixation sleeves, sliding cones and, endoscopes, as well as endoscopic accessories (e.g. forceps, electrodes).

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Robert D. Watkins

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973737

Prescription Use ✓ OR Over-The Counter _____
Per 21 CFR 801.109