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DEC 17 1997

K 973648

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: September 22, 1997
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			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			
Product Information:			
Trade name: MINI and MICRO Forceps with HF		Model number: 8390.xxx, 8391.xxx, 8393.96x, 8394.96x, 8756.xxx	
Common name: Forceps, biopsy, electric		Classification name: Endoscopic electrosurgical unit and accessories	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enact.	1 forceps/ scissors with H.F. 8383.03, .12, 930L, 930S	1 Richard Wolf
2 K935270	2 Modular Forceps and Scissors System	2 Richard Wolf
3 K935070	3 Dissecting and Grasping Forceps 3.5/ 5 mm	3 Karl Storz
4	4 Biopsy Instruments, Endoscopic Instrumentation 3.5/ 5 mm	4 Jarit

1.0 Description

The forceps with HF are part of the MICRO and MINI instrument set for laparoscopic microsurgery, particularly suitable for diagnostic, smaller interventions, outpatient, and pediatric laparoscopy.

The instruments smaller diameter is less invasive and allows better cosmetic effects than bigger diameters.

2.0 Intended Use

The forceps are used for grasping, manipulating and cutting as well as the dissection and biopsy of soft tissue/ organs under endoscopic control.

The modular scissors can also be used for cutting of suture material.

Minor hemorrhages can be coagulated using HF current, provided that products are marked accordingly.

3.0 Technological Characteristics

The forceps and scissors have comparable biocompatible device materials as former R.Wolf devices. The dimensions are smaller for very minimal invasive laparoscopy. The design of the jaws is the same, but miniaturized. The design of the handles is the same, but adapted to the smaller forceps.

The modular forceps and scissors with 3.5 mm diameter can be disassembled into jaws with shaft and handle for easy cleaning and replacement. They have a Luer connector to rinse cavities and channels of the forceps with a cleaning gun while reprocessing. The jaws are rotatable with an adjustment knob at the handle.

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 Instruments have been tested to assure that there is no breakage of the jaws or other parts of the instrument.

Mechanical load tests show that there is no permanent deformation of the forceps if used normally.

The steam sterilization tests performed by Richard Wolf show that 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 instructions manual.

By: Robert L. Casarsa Date: Sept 22, 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 17 1997

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

Re: K973648
Trade Name: MINI Forceps with HF, 3.5mm and MICRO Forceps with HF, 2mm
Regulatory Class: II
Product Code: GEI
Dated: September 22, 1997
Received: September 25, 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.

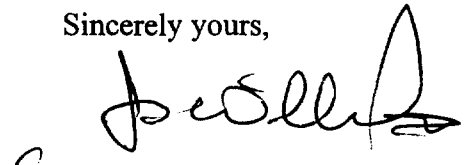
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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



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): K973648

Device Name: **MINI Forceps with HF, 3.5 mm and MICRO Forceps with HF, 2 mm**

Intended use:

The forceps are used for grasping, manipulating and cutting as well as the dissection and biopsy of soft tissue/ organs under endoscopic control.

The modular scissors can also be used for cutting of suture material.

Minor hemorrhages can be coagulated using HF current, provided that products are marked accordingly.

The modular forceps can be disassembled for easy cleaning and replacement.

Indication and Applications:

For examination, diagnostics and/or therapy by qualified, suitably trained personnel in connection with endoscopically used accessories in different medical disciplines, such as surgery, urology and gynecology, particularly suitable for outpatient and pediatric laparoscopy.

Contraindications:

There are no known contraindications directly relating to the product. The physician in charge must decide whether the intended application is possible taking into account the general condition of the patient. For further instructions please see the current technical literature.

Combinations:

The forceps have a HF connection for the use with monopolar HF units.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973648

Prescription Use ✓ OR Over-The Counter _____

Per CRF 801.109