353 Corporate Woods Parkway
Vernon Hills, Illinois 60061
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NOV 13 1997 K973341

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: September 3, 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: Monopolar Electrodes 3.5	Model number: 8379.452, .462, .482
Common name: Monopolar HF Electrodes	Classification name: Endoscopic Electrical Surgical Unit and Accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enactment	1 Coagulation electrodes 394, 376	1 Richard Wolf
2	2 Pediatric Operating Instruments	2 Karl Storz
3	3 Suction Coagulators	3 Jarit
4	4	4

1.0 Description

The electrodes are part of the MICRO and MINI instrument set for laparoscopic microsurgery. They are particularly suitable for diagnostics, smaller interventions, and out-patient and pediatric microsurgery.

2.0 Intended Use

The electrodes are used for dissection, for coagulation or removing and destroying tissue by use of unipolar high-frequency current under endoscopic view.

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3.0 Technological Characteristics

The electrodes have the same design and material as earlier R.Wolf devices. The difference between the submitted devices and its predecessors is the small diameter for minimally invasive laparoscopy.

4.0 Substantial Equivalence

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

5.0 Performance Data

No know FDA performance standards exist.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

The devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manual.

By: Robert L Casarsa Date: Sept 3, 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

NOV 13 1997

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

Re: K973341
Trade Name: Monopolar Electrodes 3.5mm
Regulatory Class: II
Product Code: GEI
Dated: September 3, 1997
Received: September 5, 1997

Dear Mr. Casarsa:

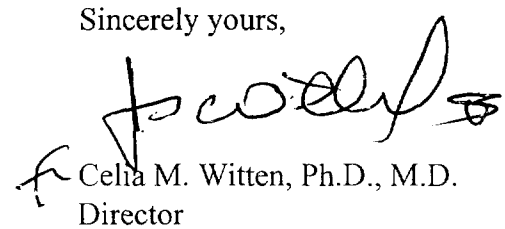
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4595. 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,



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): 973341

Device Name: **Unipolar electrodes**

Intended Use:
The electrodes are used for dissection, for coagulation or removing and destroying tissue by use of unipolar high-frequency current under endoscopic view.

Indication:
The electrodes are used for examination, diagnostics, and/or therapy by personnel who are qualified and suitably trained in connection with endoscopically used accessories in different medical disciplines, particularly suitable for outpatient and pediatric laproscopy.

Contraindications:
Currently there are no known contraindications directly related to the product. The physician in charge must determine whether the intended application is possible based on the patient's general condition. For further instruction and notes, refer to the latest specialized literature.

Combinations:
The electrodes are used in combination with unipolar HF devices, trocar sleeves, and operating endoscopes.

(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 K973341

Prescription Use X OR Over-The Counter
Per 21 CFR 801.109