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12 1999

K984304

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: August 10, 1999
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			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 L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:

Trade name: Power Cutters and Burrs for RIWO Drive System	Model number: Reusable: 8564, 8566, 8567, 8568, 8569, 8571 Single Use: 4567, 4568, 4569, 4571
Common name: Cutters and Burrs	Classification name: Cutters and Burrs

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K970088	1 RIWO Drive Generator w/ Footswitch, Motor Handles & Single Use Rotary Blades & Abraders	1 Richard Wolf GmbH
2	2	2

1.0 Description

The power Cutters and Burrs consist of a hollow, fenestrated tube, containing a rotating two-edged cylindrical blade (cutter) or an abrader (burr) that spins within the hollow tube. They are driven by a motor handle.

2.0 Intended Use

The RIWO Drive Generator with motor handle serves to drive Wolf Power Cutters and Burrs to remove tissue during endoscopic procedures.

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Indication and field of application:
For therapy with endoscopic accessories:

- in arthroscopy, e.g., for resection of meniscus, for removal of soft tissue, as well as for intra-articular severing or abrading of bone tissue, e.g., ACL or shoulder procedures
- in sinus surgery, e.g. for removal of polyps
- in spine surgery (arthroscopic mirco disectomy (AMD), spinal endsoscopy)

3.0 Technological Characteristics

- atraumatic design
- color coding
- sterile, for single use models
- multiple diameters and tip designs

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing devices sold by Richard Wolf.

5.0 Performance Data

No known performance standard exists.

6.0 Clinical Tests

No clinical tests were 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: Aug 10, 1999

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 1999

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

Re: K984304
Trade Name: RIWO Drive Generator
Regulatory Class: II
Product Code: HRX
Dated: May 14, 1999
Received: May 17, 1999

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) 594-4595. 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): K984304

Device Name: Single Use or Reusable Power Cutters and Burrs

Intended Use:
The RIWO Drive Generator with motor handle serves to drive Wolf Power Cutters and Burrs to remove tissue during endoscopic procedures.

Indication and field of application:
For therapy with endoscopic accessories:

- in arthroscopy, e.g., for resection of meniscus, for removal of soft tissue, as well as for intra-articular severing or abrading of bone tissue, e.g., ACL or shoulder procedures
- in sinus surgery, e.g. for removal of polyps
- in spine surgery (arthroscopic mirco disectomy (AMD), spinal endsoscopy)

Contraindications:
Contraindications are given in cases where the clinical condition of the patient or the specific case increases significantly the risk to the patient if motorized instrumentation is applied. This might result in an absolute or a relative contraindication.

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984304

Prescription Use X
Per 21 CFR 801.109

OR

Over-The Counter

Revised 8/10/99