3/17/99

K984521

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510(k) Summary of Safety and Effectiveness

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

Submitter:			**Date of Preparation:** December 18, 1998
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: RIWO Drive System 2302 with small motor handles		**Model number:** 2302, 8563.111, 8563.351, 8563.351 / .451 / .551	
Common name: Drive Generator, Motor Handles		**Classification name:** ENT electric surgical drill	

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 with Footswitch, Motor handles and single use rotary blades and abraders	1 Richard Wolf
2 K972584	2 Hummer ENT micro debrdier	2 Stryker
3 K973499	3 XPS Straightshot Microresector	3 Xomed
4 K953370	4 Karl Storz Paranasal Sinus Shaver	4 Karl Storz

1.0 Description

The RIWO Drive Generator is designed to efficiently drive and control different motor handles. The handle functions are controlled by a footswitch.

The motor handle is a tubular modular system. The modular system consists of:

- motor unit
- motor housing
- suction adapter (8563.111) And/Or suction /irrigation adapter (8563.311)

The suction and irrigation stream are controlled by slide valves. The motor handle is connected to the RIWO Drive 2302 by a removable cable.

2.0 Intended Use

The RIWO Drive with motor handle is used for driving Wolf rotary blades and abraders for the removal of pathological tissue during endoscopic interventions.

Simultaneous suction (evacuation) allows continuous removal of ablated tissue, with motor handle 8563.311 additionally supported by irrigation.

3.0 Technological Characteristics

RIWO Drive Generator

- four speed settings, user selected
- continuous digital display of selected and true speed
- automatic adaptation of speed range and maximum torque (current) for three different motor handles, display of speed range with LED
- acoustic and optical alarm for, 1) motor overload, 2) incorrect cable connection or interrupted cable
- footswitch, operated by surgeon, to control motion forward, reverse, oscillation (3 changes per second), speed and speed range automatically stored.
-

Motor Handle

- 360° rotation of clamping chuck for various cutting positions (8561.121 and 8562.111)
- modular construction (8563.111/.311)
- variable irrigation control with one-hand operation (8563.331)
- watertight housing and motor unit, for steam sterilization
- lightweight design
- detachable cable
- BF insulation according to IEC601-1

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 510(k) devices sold by Richard Wolf and sold by Stryker, Xomed, or Karl Storz.

5.0 Performance Data

The RIWO Drive Generator with the motor handles were tested according to the standards IEC601-1 and UL2601-1.

6.0 Clinical Tests

Clinical tests performed were not performed.

7.0 Conclusions Drawn

These devices are designed and tested to assure their safety and effectiveness when used according to the instructions manual.

By: Robert L Casarsa Date: Dec 17, 98

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 1999

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

Re: K984521
RIWO Drive Small Motor Handle
Dated: December 18, 1999
Received: December 21, 1999
Regulatory class: II
21 CFR 874.4250/Procode: 77 EQL
21 CFR 878.4820/Procode: 79 GEY

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 legally marketed predicate 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K984521

Device Name: Small Motor Handles for RIWO Drive System 2302

Intended Use:

The RIWO Drive with small motor handle is used for driving Wolf rotary blades and abraders for the removal of pathological tissue during endoscopic interventions.

Simultaneous suction (evacuation) allows continuous removal of ablated tissue, with motor handle 8563.311 additionally supported by irrigation.

Indications and Fields of Application:

For therapy with endoscopic accessories:

- in arthroscopy, e.g. for meniscus resection, removal of soft tissue, as well as intra-articular severing or abrasion of osseous tissue, e.g. ACL or shoulder procedures.
- thoracic surgery, e.g. for removing hematomas
- sinus surgery (ENT), e.g. for removing polyps or cysts.In certain cases, bone structures are removed or trimmed.
- spine surgery (arthroscopic micro disectomy (AMD), spinal endoscopsy) e.g. removal of pathological tissue.

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984521

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