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AUG 1 9 2004

RICHARD WOLF
Medical Instruments Corporation

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13.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: **June 4, 2004**
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: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:	
Trade name: Morce Scope Set with Power Control 2303 and Suction Pump 2207	Model number: 2303.011/ .901/ .911, 8564.121/ .851
Common name: Motorized Morcellator Endoscope Set with Suction Pump	Classification name: Resectoscope, Endoscope and accessories

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K970105	1 RIWO CUT Morcellator	1 Richard Wolf
2 K030082	2 Power Control 2303 with Power Stick M4	2 Richard Wolf
3 K011911	3 Suction Pump for Intracorporeal Ultrasound Lithotripter and Accessories	3 Richard Wolf
4 K982515	4 Power Drive Modell #7688PD	4 WISAP, Germany
5	5 VersaCut	5 Coherent

1.0 Description

The Morce Scope Set 8970, is a morcellation set that consist of a Morce endoscope, rotary blade, sheaths, obturators and an optional sieve. The rotary blade is designed to be inserted into the Morce endoscope, requiring one incision. The rotary blades are driven by a motorized handle, which is controlled by the Power Control Generator 2303. The suction pump 2207 removes the morcellated tissue.

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2.0 Intended Use

Morce Scope Set 8970, in conjunction with a morcellation probe, and with its sheaths and obturators, is used in the cutting (morcellation) and continuous removal of large tissue masses.

In combination with the corresponding auxiliary instruments, it can be used as a nephroscope in the disintegration and removal/aspiration of kidney and bladder stones and the removal of tumors via percutaneous (kidney) or transurethral (bladder) passages, in conjunction with intracorporeal lithotriptors e.g. operated pneumatically, by ultrasound, electro-hydraulically or by laser, under endoscopic control.

The POWER CONTROL 2303 in conjunction with POWER STICK M4 serves to drive WOLF morcellators for the continuous removal of ablated tissue in endoscopic operations.

The SUCTION PUMP is used for aspirating irrigation fluid in conjunction with a resectoscope or a morcellator following laser TURP.

3.0 Technological Characteristics

The rotary blade consists of an outer blade and a rotating inner blade with sharp toothed double edges. Simultaneous suction is possible through the inner blade.

The tissue intended for morcellation must be separated prior by laser or other techniques in the submitted Morce Scope Set as it is in the previous morcellation systems.

The POWER CONTROL 2303 is operated with motor handle POWER STICKS M4 that drives the rotary blade clock-wise, counter-clockwise or in oscillation mode when the corresponding foot pedal or front panel button is depressed

The Suction Pump 2207 is a roller pump that generates a continuous vacuum. The suction rate is limited to a preselectable value and is controlled by a flow detector.

Via the CAN-BUS interface, the POWER CONTROL 2303 and the Suction pump 2207 can be integrated into the R.Wolf RIWO NET SYSTEM with remote control, speech control, or touch-screen monitor.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices and 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, Coherent and WISAP.

5.0 Performance Data

The devices are designed to meet the standards IEC601-1: 1988 and A1 + A2 and IEC601-1-2.

6.0 Clinical Tests

No clinical tests performed.

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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: June 4, 2004

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 1 9 2004

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K041610
Trade/Device Name: Morce Scope Set 8970 with Power Control 2303 and Suction Pump 2207
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: 78 FJL; 79 GEY and JCX
Dated: June 4, 2004
Received: June 22, 2004

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5.0 INDICATIONS FOR USE

510(k) Number (if known): — K041610

Device Name: **Morce Scope Set 8970 with Power Control 2303 and Suction Pump 2207**

Intended use:

Morce Scope Set 8970:
The Morce Scope Set, in conjunction with a morcellation probe, and with its sheaths and obturators, is used in the cutting (morcellation) and continuous removal of large detached tissue masses.

In combination with intracorporeal lithotriptors, e.g. operated pneumatically, by ultrasound, electro-hydraulically or by laser under endoscopic control, it can be used as a nephroscope in the disintegration and removal/aspiration of kidney and bladder stones and the removal of detached tumors from the bladder.

Power Control 2303:
The POWER CONTROL 2303 in conjunction with POWER STICK M4 serves to drive WOLF morcellators for the continuous removal of ablated tissue in endoscopic operations.

Suction Pump 2207:
The SUCTION PUMP is used for aspirating irrigation fluid in conjunction with a resectoscope or a morcellator following laser TURP.

Indication and Field of Use:

When used as a Morce Scope: for therapy via the transurethral passage after a TURP (TransUrethral Resection of the Prostate) procedure.
When used as a nephroscope: for diagnosis and therapy of urolithiasis .
In both cases the product must be used in conjunction with endoscopic accessories. The product may only be applied by adequately qualified and trained medical personnel.

Revised 8/18/04

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

Concurrence of CDRH Office of Device Evaluation (ODE)

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

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041610

(Optional Format 1'2-96)