SEP 1 7 2001

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RICHARD WOLF
Medical Instruments Corporation

353 Corporate Woods Parkway
Vernon Hills, IL 60061
Phone: 847-913-1113
Customer Service: 800-323-WOLF
www.richard-wolf.com

12.0 510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: June 18, 2001	
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: Suction pump for Intracorporeal Ultrasound Lithotripter and accessories		Model number: 2207.xxx	
Common name: Suction Pump		Classification name: Gastroenterology-urology evacuator	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 pre-enact.	1 Suction pump 2017.00	1 Richard Wolf
2 K011065	2 Ultrasound Lithotriptor 2271	2 Richard Wolf

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1.0 Description

The Suction pump 2207 is a roller pump that generates a continuous vacuum for aspirating the particles and liquids during ultrasound lithotripsy into a fluid trap (bottle).

2.0 Intended Use

Suction pump 2207 with its accessories is used to aspirate liquids in ultrasound lithotripsy. It is designed for combined use with the ultrasound generator 2271 for aspiration of disintegrated kidney stones, bladder stones and ureter stones and the liquid involved.

3.0 Technological Characteristics

The vacuum applied to the fluid trap (and with it the suction rate) is continuously measured and feedback-controlled by software.
The suction is monitored by a flow detector.
A safety circuit interrupts the suction if the cover of the pump housing is opened.
The suction pump has an interface to our Intracorporeal Ultrasound Lithotripter 2271 for increasing the suction rate during activation of ultrasound.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the predicate 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 and competitors.

5.0 Performance Data

The Suction pump 2207 is conforming to standards UL 2601 and IEC 601-1.

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: June 18, 2001

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 2 0 2001

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

Re: K011911
Trade/Device Name: Model 2270.011 Suction Pump for Intracorporeal Ultrasound Lithotriptor and Accessories
Regulation Number: 21 CFR §876.4480
Regulation Name: Electrohydraulic Lithotriptor
Regulatory Class: II
Product Code: 78 FFK
Dated: June 18, 2001
Received: June 19, 2001

Dear Mr. Casarsa:

This letter corrects our substantially equivalent letter of September 17, 2001, regarding the Model 2270 Suction Pump for Intracorporeal Ultrasound Lithotriptor and Accessories which was listed as a model 2270 Ultrasound Generator.

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). 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 continue market your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to 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 Part 809.10 for in vitro diagnostic devices), Please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2031 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmanain.html.

Sincerely yours,

David A. Lepson

for 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): — K011911

Device Name: Suction pump for Intracorporeal Ultrasound Lithotripter and accessories

Intended use: Suction pump 2207 with its accessories is used to aspirate liquids in ultrasound lithotripsy. It has been designed for combined use with the ultrasound generator 2271. In conjunction with ultrasound generator 2271 the suction pump is exclusively used for aspiration of disintegrated kidney stones, bladder stones and ureter stones and the liquid involved.

Contraindications: Contraindications directly related to the product are presently unknown. On the basis of the patient's general condition the doctor in charge must decide whether the planned use is possible or not. For further information see the latest medical literature.

Combinations: The R.Wolf "Suction Pump 2207" is specially designed for use with an ultrasound lithotriptor. It is specially designed for combined use with the WOLF US-LITHO 2271.
If the suction pump is to be used in conjunction with other ultrasound lithotriptors (other marks, brands), the user must check whether the device combination can reach and maintain the required functions on a continuous basis.

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011911

Prescription Use ✓