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SEP 10 1998

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

K981334

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: April 8, 1998
Company / Institution name: **Richard Wolf Medical Instruments Corp.**			FDA establishment regulation 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: Laparo CO_2 Pneu	Model number: 2232.601, .611
Common name: Automatic Laparoscopic CO_2 Insufflator	Classification Name: Laparoscopic Insufflator

Information on devices to which substantial equivalence is claimed:		
510(k) Number	Trade or proprietary or model name	Manufacturer
1 K934884	1 2231 Laparoscopic Insufflator	1 Richard Wolf
2	2 System 4000	2 CABOT
3	3 Medicam 900	3 MP Video
4	4 26012C	4 Karl Storz

1.0 Description

The Laparo CO_2-Pneu 2232 supplies CO_2 gas from cylinders or central gas supplies to dilate the abdomen by CO_2 gas insufflation.

2.0 Intended Use

The Laparo CO2-Pneu generates and maintains pneumoperitoneum CO2 gas and can be used in diagnostic and operative laparoscopy.

3.0 Technological Characteristics

The pressure and flow values are checked by microprocessor control. A series of independent safety devices guarantee safe and problem-free insufflation.

The intra-abdominal pressure can be steplessly preselected between 5 mmHg and 25 mmHg. The pressure is reduced if the intra-abdominal pressure is higher than the preselected value.

The flow rate can be preselected between 1 l/min and 20 l/min in steps of 1 l/min.

The measured values can be displayed on-screen in order to document the pressure, flow and gas consumption values during intervention via video equipment.

4.0 Substantial Equivalence

The Laparo CO_2-Pneu 2232 is substantially equivalent to existing 510(k) devices sold by Richard Wolf and to various existing laparoscopic insufflators from Cabot, MP Video, and Karl Storz.

The differences do not affect the safety or effectiveness of the device.

5.0 Performance Data

Performance data not generated.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

Laparo CO_2-Pneu 2232 was designed and tested to guarantee the safety and effectiveness furing the expected lifetime of the device if it is used according to the instruction manual.

By: Robert L. Casarsa Date: Apr 1, 1998

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 1998

Mr. Robert L. Casarsa
Manager of Quality Assurance
RICHARD WOLF MEDICAL INSTRUMENTS CORP.
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K981334
Laparo CO_2 - Pneu 2232 (Laparoscopic Insufflator)
Dated: June 26, 1998
Received: June 27, 1998
Regulatory Class: II
21 CFR 884.1730/Procode: 85 HIF

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) 594-4613. Additionaliy, 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,

Lillian Yin, Ph.D.
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): K981334

Device Name: Laparo CO_2 Pneu 2232

Intended Use:

The Laparo CO_2-Pneu generates and maintains pneumoperitoneum CO_2 gas and can be used in diagnostic and operative laparoscopy.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K981334

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