K991906

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NOV 23 1999

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			**Date of Preparation:** May 14, 1999
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: 2232.621, .631
Common name: Automated 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 K981334	1 Laparo CO_2 Pneu 2232 (20 L)	1 Richard Wolf
2 K955073	2 Thermoflator 264320 20	2 Karl Storz
3	3	3
4	4	4

1.0 Description

The Laparo CO_2-Pneu 2232 supplies CO_2 gas from cylinders or central gas supplies to dilate the abdomen by the CO_2 gas insufflation. The gas pressure and the flow rate are adjusted by the user and electronically controlled.

2.0 Intended Use

The Laparo CO_2-Pneu automatic insufflator generates and maintains pneumoperitoneum under CO_2 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 number of independent safety devices provide safe and problem-free insufflation.

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

The flow rate can be preselected between 1 L/minute and 30 L/minute at a pace 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.

An electronic circuit, integrated into the insufflation tube, warms the gas to body temperature.

4.0 Substantial Equivalence

The Laparo CO_2-Pneu is substantially equivalent to existing 510(k) devices sold by Richard Wolf and Karl Storz.

5.0 Performance Data

No performance data 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 during the expected life time of the device when used according to the instruction manual.

By: Robert L. Casarsa Date: May 18, 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

NOV 23 1999

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

Re: K991906
Laparo CO_2 Pneu 2232 Automatic Insufflator
Dated: September 1, 1999
Received: September 2, 1999
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 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): K991906

Device Name: Laparo CO_2-Pneu Automatic Insufflator

Intended Use:

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

Contraindications:

The use of this device is contraindicated if laparoscopy is contraindicated.

Warning: The device has a high flow rate. The device is not suitable for hysteroscopy. Do not use this device to inflate the cavum uteri.

Contraindications for the patient resulting from the general findings, which are described in the relevant literature must be observed.

Possible Combinations:

Important! In addition to the product instruction manual, be sure to observe the instruction manuals of the products used in combination with this product.

Electromagnetic interference or other influences which may occur between the product and other products may lead to defects or malfunctions.

Warning! Danger of potentially fatal gas or air embolism. Purge the connection tubes thoroughly with CO_2 before every use. The use of devices using additional gaseous media in combination with the Laparo CO_2-Pneu automatic insufflator lies exclusively in the responsibility of the user.

(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 K991906

Prescription Use X OR Over-The Counter

Per 21 CRF 801.109

892

Warning! There is danger of intra-abdominal pressure when a second gas source is used.

When argon plasma coagulations are used, it is vital for the user to also have additional visual or manual pressure monitoring available, as there is a potential risk that the pressure monitoring or ventilation of the Laparo CO_2-Pneu is deactivated, e.g. by a kinked insufflation tube or a closed instrument port (stopcock). The preselected gas flow rate of argon plasma coagulatiors should not exceed 2 l/min. Activate the argon plasma coagulator only for short periods of time.

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