Richard Wolf Medical Instruments Corporation

OCT 2 2 1997

K971420

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353 Corporate Woods Parkway
Vernon Hills, Illinois 60061
Telephone: 847.913.1113
Fax: 847.913.1488

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: April 16, 1997
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: Mini Laparoscopes	Model number: 8755.xxx
Common name: Veress Cannula Spring Loaded, Telescope	Classification name: Set Laparoscopy

Information on devices to which substantial equivalence is claimed:		
510(k) Number	Trade or proprietary or model name	Manufacturer
1 K962799	1 Mini Laparoscopes	1 Richard Wolf M.I.C.
2	2 Surgy Needle VN-1500	2 IMAGYN
3	3 Veress Needle AN3MM	3 Ethicon
4	4 OMS-PNS Pixie Microendoscope	4 Origin

1.0 Description

Cannula and tubes are made of medical grade stainless steel and chrome plated brass.

Telescopes are made of medical grade stainless steel (sleeve), glass-lenses, glass-fibers, brass chrome plated (housing), and plastic (eyepiece).

2.0 Intended Use

The Microendoscope system is used to apply and maintain pneumoperitoneum for laparoscopic procedures and to provide access and visualization for diagnostic and therapeutic purposes for laparoscopic and hysteroscopic procedures.

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3.0 Technological Characteristics

As the intended use describes, the set is miniaturized in diameter and length for minimally invasive laparoscopy. The veress cannula and the tubes are larger in diameter and longer in working length. The telescopes are shorter in length and smaller in diameter.

4.0 Substantial Equivalence

The submitted devices are substantially equivalent to existing pre-enactment devices sold by Richard Wolf and 510(k) devices sold by Imagyn, Ethicon, and Origin.

5.0 Performance Data

Instruments have been tested to assure the function of the spring loaded cannula and the possibility of steam autoclaving.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

The mentioned R. Wolf Mini Laparoscopy devices are substantially equivalent to existing devices on the market. They have been tested to allow safe usage with no significant changes during the standard lifetime when used according to instructions.

By: Robert L Casarsa Date: APR 15 97

Robert L. Casarsa
Quality Assurance Manager

RICHARD WOLF

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1997

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

Re: K971420
Microendoscope System (Mini Lap) for OB/GYN Use
Dated: July 31, 1997
Received: August 1, 1997
Regulatory Class: II
21 CFR §884.1690 & 884.1720
Product Code: 85 HIH & HET

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 requirement, 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/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): K971420

Device Name: Microendoscope System (Mini Lap) for OB/GYN Use

Intended Use:

The Microendoscope system is used to apply and maintain pneumoperotoneum for laparoscopic procedures and to provide access and visualization for diagnostic and therapeutic purposes for laparoscopic and hysteroscopic procedures.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Robert R Satterfield

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971420

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