K003417/S1
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RICHARD WOLF
Medical Instruments Corporation

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510(k) Summary of Safety and Effectiveness

Submitter:			**Date of Preparation:** October 26, 2000
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: Mini Fiber Laparoscope/Hysteroscope Set 8754.xxx	Model number: 8754.xxx,.....see section 4: 'submitted devices'
Common name: Laparoscope/Hysteroscope and accessories	**Classification Name:** Laparoscope/Hysteroscope Set

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K971420	1 Microendoscope System (Mini Lap) for OB/GYN use (8755)	1 Richard Wolf
2 K962799	2 Mini Laparoscopes (8755)	2 Richard Wolf

1.0 Description

The Mini Fiber Laparoscope/Hysteroscope Sets consist of:

- Endoscope with fiberoptic cable, cold light connector, threaded, removable/snap-on eye piece funnel and automatic locking mechanism.

- Veress cannula with insufflation stopcock and automatic locking mechanism
- Outer sheath with insufflator stopcock and automatic locking mechanism.

The Endoscopes and Veress cannulas can be attached to the outer sheaths.

2.0 Intended Use

TheMinature Laparoscope Set serves to apply and maintain pneumoperitoneum and to visualize the inside of the patient via surgically created passages. The Mini Hysteroscope serves to visualize the cervical channel and the Cavum Uteri via the natural passage.

3.0 Technological Characteristics

The submitted Mini Endoscope Sets are substantially equivalent to the legally marketed devices sold by Richard Wolf in K962799 (Laparoscopy) and K971420 (Hysteroscopy).
The differences are:

- more image fibers for better optical resolution
- automatic locking mechanism versus bayonet connection to improve user comfort
- threaded removable/snap-on eyepiece funnel versus fixed
- minor changes in diameter and working length
- change in material (phynox,titanium)

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the equivalent devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing devices sold by Richard Wolf.

5.0 Performance Data

The submitted devices are in conformance with the relevant provisions of the Medical Device Directive 93/42/EEC.

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 instruction manual.

By: Robert L. Casarsa
Robert L. Casarsa
Quality Assurance Manager

Date: Oct 26, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2001

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

Re: K003417
Mini Fiber Laparoscope/Hysteroscope Set 8754.xxx
Dated: March 2, 2001
Received: March 5, 2001
Regulatory Class: II
21 CFR §884.1720/Procode: 85 HET
21 CFR §884.1690/Procode: 85 HIH

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) 594-4639. 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 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,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use

510(k) Number (if known): K003417

Device Name: Mini Fiber Laparoscope/Hysteroscope Set

Intended Use:

The Minature Laparoscope Set serves to apply and maintain pneumoperitoneum and to visualize the inside of the patient via surgically created passages. The Mini Hysteroscope serves to visualize the cervical channel and the Cavum Uteri via the natural passage.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003417

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter _____