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MAR - 6 2000

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

K994363

# 510(k) Summary of Safety and Effectiveness

| Submitter | |
|---|---|
| **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:** | **State/Province:** | **Country:** | **ZIP / Postal Code:** |
|---|---|---|---|
| Vernon Hills | Illinois | USA | 60061 |

| | |
|---|---|
| **Contact name:** | Mr. Robert L. Casarsa |
| **Contact title:** | Quality Assurance Manager |

| Product Information | |
|---|---|
| **Trade name:** Minimally Invasive Spinal Surgery Set | **Model number:** 8972.xxx, 8973.xxx, and others |
| **Common name:** Spinal Arthroscopic Set | **Classification name:** Arthroscope and Accessories |

**Information on devices to which substantial equivalence is claimed:**

| 510(k) Number | Trade or proprietary or model name | Manufacturer |
|---|---|---|
| 1 K973405 | 1 Yeung Endoscopic Spine System | 1 Richard Wolf |
| 2 K960222 | 2 Instruments for Percutane Discetomy | 2 Richard Wolf |
| 3 | 3 Endoscopic Spine Instruments | 3 Sofamor Danek |
| 4 | 4 Miaspas Mini ALIF Instrument Set for Fusion | 4 Aesculap |

## 1.0 Description

MISS is an acronym for Minimally Invasive Spinal Surgery. The operating technique is comparable to laparoscopic and thorascopic procedures.

Punches, rongeurs, osteotomes, elevators, spoons, curettes, probes, bone pusher, block applicator, compaction tube, and swivel arm are primarily used for transthoracic and transabdominal approaches to the spine.

**2.0 Intended Use**

The MISS instrument set is designed for transthoracic and transabdominal approaches to the spine.

**3.0 Technological Characteristics**

The devices are comparable to existing devices by Richard Wolf, Sofamor Danek, and Aesculap.

**4.0 Substantial Equivalence**

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

**5.0 Performance Data**

No performance standards are known.

The conformity assessement relevant to provisions of European Device Directive 93/42/EEC is pending.

**6.0 Clinical Tests**

Clinical tests were not performed.

**7.0 Conclusions Drawn**

These devices are designed and tested to assure their safety and effectiveness when used according to the corresponding instruction manual.

By: Robert L. Casarsa Date: Dec 21, 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

MAR - 6 2000

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

Re: K994363
Trade Name: Minimally Invasive Spinal Surgery Set
Regulatory Class: II
Product Code: HRX
Dated: December 22, 1999
Received: December 27, 1999

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) 594-4595. 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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

[redacted]

510(k) Number (if known): K994363

Device Name: Minimally Invasive Spinal Surgery Set (MISS)

**Intended Use:**

The MISS instrument set is designed for transthoracic and transabdominal approaches to the spine.

**Hand instruments,** such as **osteotome, elevator, hook probe, spoon, curette, punch, compunction tube with obturator,** and **plug applicator** are used for endoscopically controlled dissection, exploration, and manipulation of tissue through natural or surgically created passages.

**Rongeurs** and **punches** are used under endoscopic control, to grasp, manipulate, and cut, as well as for the dissection and biopsy of tissue, organs, or foreign bodies.

**Suction irrigation punches** are used for endoscopically controlled punching and removal of tissue through natural or surgically created passages.

**Indications and Application:**

For examination, diagnosis, and / or therapy by personnel trained and qualified in connection with endoscopically used accessories in various medical disciplines, such as orthopedic and spinal surgery.

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

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994363

Prescription Use X
Per 21 CFR 801.109

OR

Over-The Counter

**Contraindications:**

Contraindications directly related to the product are currently unknown.

The attending physician must determine if the intended application is appropriate based on the general condition of the patient.

For further instructions, please refer to the current technical literature.

**Combinations:**

The endoscopes are used in connection with endoscopes and endoscopic accessories.

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

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Prescription Use_____ OR Over-The Counter_____

Per 21 CFR 801.109