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Vernon Hills, Illinois 60061
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K973405

MAR 13 1998

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: January 12, 1998
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: Discoscope Set		Model number:	
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 K930191	1 MED Microendoscopy Disectomy System	1 Sofamor Danek
2 K922519	2 Kambin Arthroscopic Microdiscetomy System	2 Dyonics
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7
8	8	8

1.0 Description

The set consists of a telescope, forceps, sheath, obturator, adapter, tephine, punch, scissors, dilator, cannula, and caps. It is designed to be compatible with other available systems, but with increased emphasis on superior quality imaging. The scope system is designed to allow for clear visualization of spinal anatomy and pathology through its unique multichannel flow integrated system and working channels.

2.0 Intended Use

The Yeung Endoscopic Spine System is indicated for the visualization and removal of herniated discs in the lumbar region.

3.0 Technological Characteristics

- Designed to allow for clear visualization of spinal anatomy and pathology through its unique multichannel flow integrated system and working channels..

4.0 Substantial Equivalence

The Richard Wolf Yeung Endoscopic Set is substantially equivalent to the following devices:

- Richard Wolf 8986.401 Operative Scope
- Sofamor Danek MED Endoscope
- Smith & Nephew Richards AMD VideoDiscoscope

All devices have the same intended use.

5.0 Performance Data

None

6.0 Clinical Tests

None

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 Date: Jan 9, 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

MAR 13 1998

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

Re: K973405
Trade Name: Yeung Endoscopic Spine System
Regulatory Class: II
Product Code: HRX
Dated: January 9, 1998
Received: January 13, 1998

Dear Mr. Casarsa:

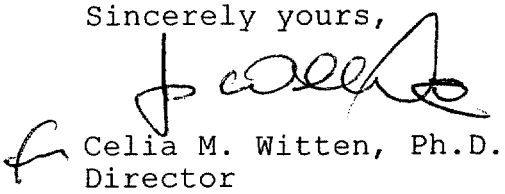
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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) 594-4659. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____
Device Name: Yeung Endoscopic Spine System

Indications for Use:

Indications for Use:
The Yeung Endoscopic Spine System is indicated for the visualization and removal of herniated discs in the lumbar region.

(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 General Restorative Devices
510(k) Number K973405

Prescription Use X
Per CFR 21 CFR 801.109

OR

Over-The-Counter Use_____