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SEP 24 1999

K992526

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: July 26, 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: Flexible nasopharyngo-laryngoscope and Flexible bronchoscope	Model number: 7222, 7223, 7224, 7265, 7325, 7330
Common name: Naso-pharyngo-laryngo-fiberscope and broncho-fiberscope	Classification Name: Nasopharyngo-laryngoscope and bronchoscope

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K980401	1 Flexible fiberscopes and accessories (urology, surgery, and gynecology)	1 Richard Wolf
2 K951196 /K921707	2 Naso-pharyngo-laryngo-esophago fiberscopes FNL-7, FNL-10, FNL-13, FNL-15	2 Pentax
3 K811053 / K951199	3 Broncho deluxe fiberscoe FB-10, FB18	3 Pentax

1.0 Description

The flexible bronchoscopes and nasopharyngo-laryngoscopes consist of three parts: 1) flexible insertion part with or without a working channel, 2) control part for the deflection of the tip, and 3) an eyepiece for direct view or connection to a video camera.

2.0 Intended Use

The **flexible nasopharyngo-laryngoscope** and the **flexible bronchoscope** are used to visualize body cavities via natual passages.

The **bottom electrode** is used for tissue and vessel coagulation by means of high frequency current under endoscopic view.

3.0 Technological Characteristics

They are equivalent to the flexible endoscopes cleared in K980401, *Flexible Fiberscopes and Accessories* for urology, surgery, and gynecology. The fiberscopes in the submission use the same basic design and device material as submitted in K980401. Some flexible bronchoscopes and nasopharyngo-laryngoscopes have a fixed light cable instead of a removable light cable; some of them have a working channel.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf and Pentax.

5.0 Performance Data

No performance standards are known.
The fiberscopes and the button electrode were built according to the specifiecied standards IEC601-1, IEC601-2-18, and IEC601-2-2.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are 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: 7/22/99

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 24 1999

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

Re: K992526
Device: Flexible Nasopharyngo-Larynogoscope and Bronchoscope
Dated: July 28, 1999
Received: July 26, 1999
Classification Regulation: 77 EOB, 21 CFR 874.4760
77 EOQ, 21 CFR 874.4680
Regulatory Class: II

Dear Mr. Casarsa:

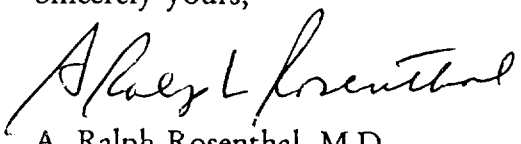
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 at (301) 443-6597.

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K992526

Device Name: Flexible Nasopharyngo-Laryngoscope and Bronchoscope

Intended Use:

The **flexible nasopharyngo-laryngoscope** and the **flexible bronchoscope** are used to visualize body cavities via natual passages.

The **button electrode** is used for tissue and vessel coagulation by means of high frequency current under endoscopic view.

Indication and Field of Application:

For examination, diagnosis, and /or therapy in connection with endoscopic accessories / auxiliary instruments through the working channel of the endoscope. This instruement is used in the medical discipline of ENT (e.g. naso-pharynxngeal cavity - larynx / trachea and bronchial branch by adequately trained and qualified medical personnel.

IMPORTANT! The product dimensions must correspond to the anatomic conditions, i.e., the correct flexible nasopharyngo-laryngoscope or flexible bronchoscope must be selected for the planned intervention.

(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 Ophthalmic Devices
510(k) Number K992526

Prescription Use ✓ OR Over-The Counter

Per 21 CRF 801.109