



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

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

JUL 27 2015

Re: K991178
Trade/Device Name: Flexible Fiberscope
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated (Date on orig SE ltr): April 5, 1999
Received (Date on orig SE ltr): April 7, 1999

Dear Mr. Casarsa,

This letter corrects our substantially equivalent letter of June 11, 1999.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K991178

Device Name: Flexible Fiberscope

Intended Use:

The flexible fiberscopes are used to examine body cavities and hollow organs via natural accesses or surgically created accesses.

Indications and Field of Application:

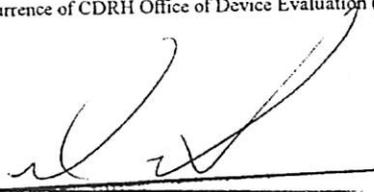
For examination, diagnosis, and / or therapy in connection with endoscopic accessories and auxiliary instruments, in particular, for intracorporal flexible lithotripsy probes, e.g., pneumatic or electrohydraulic, used through the working channel of the instrument.

The instruments are used in the medical disciplines of urology, surgery, gynecology, and ENT by adequately trained and qualified medical personnel. Applications to the heart, the central nervous system, and the circulatory systems are excluded.

Important! Product dimensions must correspond to the anatomic requirements, i.e., use the flexible fiberscope appropriate to the medical discipline.

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

Concurrence of CDRH Office of Device Evaluation (ODE)



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Contraindications:

Contraindications directly related to the product are currently unknown. Based on the patient's general condition, the attending physician must determine if the application is appropriate. For further information refer to the latest medical literature.

Combinations:

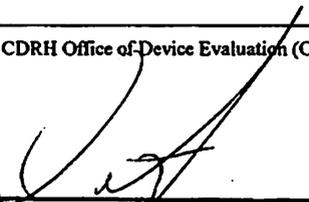
The flexible fiberscopes are used in combination with light sources and flexible light cables, video cameras, or reflex cameras and lenses/objectives, suction irrigation devices, as well as endoscopic accessories (flexible lithotripsy probes, forceps, HF instruments, sheaths laser fibers, etc.).

Caution! Ensure devices used in combination are compatible n their intended use and relevant specifications, e.g., working length, diameter, etc. Comply with the device instruction manuals used in combination with the submitted devices.

Important! If the fiberscopes are used as uretero-renoscopes or in choledochus revisions, they must be placed via a guide wire.

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JUN 11 1999

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 Vernon Hills, Illinois 60061
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RICHARD WOLF
 MEDICAL INSTRUMENTS CORPORATION



510(k) Summary of Safety and Effectiveness

Submitter:		Date of Preparation: April 5, 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 Fiberscope		Model number: 7331.001	
Common name: Flexible Fiberscopes		Classification Name: Flexible Endoscopes	
Information on devices to which substantial equivalence is claimed:			
510(k) Number	Trade or proprietary or model name	Manufacturer	
1 K980401	1 Flexible Fiberscopes	1 Richard Wolf	
2 K963855	2 Compact Operating Ureterscopes & Uretero-Renoscopes Devices (URS)	2 Richard Wolf	
3	3	3	
4	4	4	
5	5	5	
6	6	6	

1.0 Description

The flexible fiberscopes consist of a flexible insertion part, a control part, a bent eyepiece for direct view or connection of a video camera and straight working channel, especially for the use with lithotripsy probes.

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2.0 Intended Use

The flexible fiberscopes are used to examine body cavities and hollow organs via natural accesses or surgically created accesses.

3.0 Technological Characteristics

There are no significant technological characteristic changes to the new devices when compared to the existing devices.

The tip of the sheath has an active 130° / 160° up/down. The image is transmitted via objective, fiber bundle and eyepiece for direct view or connection of a video camera. The straight working channel is used for procedures such as lithotripsy and biopsy removal while simultaneously providing irrigation. The bent eyepiece funnel can be moved to the right or left. Auxiliary instruments, such as gaping forceps, stone extractors, or HF button electrodes are inserted by a proximal mounted insertion cock with supply and discharge. A leakage test unit or a gas sterilization valve can be connected to an attachment of the fiberscope.

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 pre-enactment and 510(k) devices sold by Richard Wolf (K980401, K963855).

5.0 Performance Data

No known FDA performance standard exists.

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: Mar 31, 99