DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20904

Premarket Notification [510(k)] Review
Corrected Substantial Equivalence Letters – New Product Codes

K990397

Date: 1/30/2014
To: The Record
From: Tuan Nguyen, Biomedical Engineer
Kellie Straughn (Clerk Typist), DRGUD

Office: ODE
Division: DRGUD
Branch: ULDB

510(k) Holder: K990397

Device Name: Flexible Fiberscopes and Accessories

Previous Product Code: HRX, KOG

New Product Code: HRX

The product code KOG Endoscope and/or accessories under the regulation 876.1500 Endoscope and accessories has been used extensively to include a large variety of medical devices associated with endoscopes. Subsequent to the generation of KOG additional product codes have been generated that group similar devices into more specific groups. It was decided that the product code KOG would be no longer used and that all endoscopes and/or accessories would use the more specific product codes.

Ms Cheryl Mackey (Program Analyst, DRUGD) identified the past 510(k)s that included the product code KOG, and Ms Christine Lee (Assistant Director Program Operations, DRGUD) assigned the new procode(s). Correction letters will be generated by Kellie Straughn (Clerk Typist) to update these devices using the new product codes.

Tuan Nguyen -A
2014.01.30 09:42:53 -05'00'

Tuan Nguyen, Biomedical Engineer, ULDB

1/30/2014
Date

Digital Signature Concurrence Table	
Reviewer Sign-Off	Christine Lee
Branch Chief Sign-Off	Glenn Bell
Division Sign-Off	Benjamin R. Fisher -S

Template Name: Corrected Substantially Equivalent Letter: Classified and Not Classified; v2013-04-02

---------- REMOVE BELOW WHEN USING TEMPLATE ----------

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
9/25/12	Edwena Jones	Added digital signature format
12/12/2012	Margaret McCabe Janicki	One digit was missing from 4-digit ZIP code extension in letterhead ("002" should read "0002"). Revised to fix this.
04/02/2013	Sara Aguel	Clarified letter instructions; added OIR option in signature block. Added option for IVD labeling regulation. Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA. Added sentence that starts "Please note: CDRH does not evaluate information related to contract liability warranties..." to be consistent with language in K1(A) SE letter. Added instructions to "Re: [510(k) NUMBER]" section to be consistent with language in K1(A) SE letter.
4/12/2013	Margaret McCabe Janicki	Fixed typos in paragraph 1, final sentence: "We remind you; however, that...misleading" – replaced the incorrect semicolon with a comma and added a period at the end of the sentence.

cc: DCC – sign-off & original
ODE/DRGUD/ULDB – (GBB)

Final: KAS:kas

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUL 27 2015

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

Re: K990397
Trade/Device Name: Flexible Fiberscopes and Accessories
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated (Date on orig SE ltr): August 11, 1999
Received (Date on orig SE ltr): August 12, 1999

Dear Mr. Casarsa,

This letter corrects our substantially equivalent letter of October 25, 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

[redacted]

510(k) Number (if known): K990397

Device Name: Flexible Fiberscopes and Accessories

Intended Use:

Flexible Fiberscope: For examination, diagnosis, and/or therapy in connection with endoscopic accessories and auxiliary instruments used through the working channel of the instrument for use in lumbar spine applications.

Flexible Biopsy Forcep: Used to obtain small biopsies from tissue

Electrodes: Used for unipolar coagulation.

Field of Application:

The instruments are designed to be used by adequately trained and qualified medical personnel in the fields of spine, urology, surgery, gynecology, and ENT.

IMPORTANT! The product dimensions must correspond with the anatomic proportions, i.e., the correct flexible fiberscope must be selected for the medical procedure.

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990397

Prescription Use ✓ OR Over-The Counter ____
Per 21 CFR 801.109

Revised 9/14/99

353 Corporate Woods Parkway
Vernon Hills, Illinois 60061
Phone: 847.913.1113
Fax: 847.913.1488

OCT 25 1999

K990397

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter:			**Date of Preparation:** February 5, 1999
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: Flexible fiberscopes and accessories		**Model number:** 7265.001, 7305.xxx, 7321.xxx, 7325.xxx, 7330.xxx	
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 K962172	1 Flexible Mini-Fiberscopes	1 Richard Wolf
2	2 LASE Flexible Endoscope	2 Clarus
3 K971455	3 SITEprobe diagnostic spinal endoscope	3 Clarus
4 K946087	4 The Inclusive™ Endoscope System	4 Sofamor Danek

1.0 Description

The flexible endoscope consists of an eyepiece, with a focusing ring for direct view or connection to a video camera, a lever to control the flexible tip of the scope, and the flexible insertion portion.

2.0 Intended Use

Flexible fiberscopes are used for examination, diagnosis, and/or therapy in connection with endoscopic accessories and auxiliary instruments used through the working channel of the instrument for use in lumbar spine applications.

3.0 Technological Characteristics

There are no significant technological changes or characteristics to the new devices compared to the existing devices.

The tip of the sheath has an active deflection up to 360°, depending on the fiberscope. The deflecting position can be locked with a brake on some fiberscopes. The image is transmitted via objective, fiber bundle and eyepiece for direct view or connection to a video camera. The total number of pixels and the fibers per mm^2 are increased to get an image with higher resolution. Biopsy material can be taken by the wide working channel, which is simultaneously used for irrigation. Auxiliary instruments such as forceps are inserted via a proximal mounted insertion cock with supply and discharge.

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 pre-enactment and 510(k) devices sold by Richard Wolf in the urology branch. In addition, the submitted devices are substantially equivalent to devices sold by Clarus, and Sofamor Danek.

5.0 Performance Data

No known FDA performance standard exists.

6.0 Clinical Tests

Clinical tests performed were not performed.

7.0 Conclusions Drawn

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

By: Robert L. Casarsa Date: Feb 5, 99

Robert L. Casarsa
Quality Assurance Manager