DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 11, 2017

Richard Wolf Medical Instruments Corporation
Mr. Mike Loiterman
US Head of Regulatory - QA/QC
353 Corporate Woods Parkway
Vernon Hill, Illinois 60061

Re: K161204
Trade/Device Name: ENDOCAM Flex HD Camera System 5521
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FET
Dated: December 15, 2016
Received: December 16, 2016

Dear Mr. Loiterman:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161204

Device Name
ENDOCAM® Flex HD Camera System 5521

Indications for Use *(Describe)*

The ENDOCAM Flex HD Controller has been designed for video endoscopy and can be used for both diagnostic and therapeutic interventions.
The camera controller has an HDMI output suitable for connecting an image output device (monitor).
This product is designed exclusively for use by specialized medical personnel and may only be applied by medically qualified and adequately trained persons.

The 1-chip HD camera head 5521902 is used for diagnostic and therapeutic operations in conjunction with ENDOCAM Flex HD Controller 5521101.
This product is designed exclusively for use by specialized medical personnel and may only be applied by medically qualified and adequately trained persons.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(k) Summary

Submitter:			Date of Preparation: April 27, 2016
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. Mike Loiterman			
Contact title: US Head of Regulatory - QA/QC			
Parent Company:			
Company / Institution name: **Richard Wolf GmbH**			FDA establishment registration number: 96 111 02
Street address: Pforzheimer Str. 32			
City: Knittlingen	State/Province: Baden-Württemberg	Country: Germany	ZIP / Postal Code: 75438
Product Information:			
Trade name: ENDOCAM® Flex HD camera controller 1-CHIP ENDOCAM® Flex HD Camera Head		Model numbers: 5521101 5521902	
Common name: Endoscopic Video Imaging System/Component, Gastroenterology-Urology		Classification name: Endoscope and Accessories, Class II (21 CFR 876.1500, Product Code FET)	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
K080977	3 CCD HD ENDOCAM® 5550 Endoscopic Video camera system	Richard Wolf Medical Instruments Corporation
K130423	THE RICHARD WOLF ENDOCAM LOGIC HD CAMERA SYSTEM 5525	Richard Wolf Medical Instruments Corporation

5.1 Description

The Richard Wolf ENDOCAM® Flex HD Camera System 5521 is an endoscopic camera system for rigid, semi-rigid, and flexible endoscopes.

The camera system consists of:

- **ENDOCAM® Flex HD Controller (5521101)**
- **1-Chip ENDOCAM® Flex HD Camera Head (5521902)**

The ENDOCAM® Flex HD Camera System is used to capture and display still and video images of endoscopic or general surgical applications. Devices are used in conjunction with other ancillary equipment such as endoscopes, light sources, and monitors.

The ENDOCAM® Flex HD Camera System 5521 does not have a graphical user interface (GUI). All available functions are controlled via two buttons on the 1-Chip ENDOCAM® Flex HD Camera Head 5521902.

Devices included in the ENDOCAM® Flex HD Camera System 5521 are reusable and do not require sterilization before use because there is no direct / in-direct patient contact. Methods of cleaning, disinfection, and sterilization are detailed in the Instruction for Use Manual.

These instructions were developed by Richard Wolf using standards outlined in ANSI / AAMI ST81: 2004/ (R) 2010 and FDA's Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", issued on: March 17, 2015.

This product is exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately trained persons.

5.2 Indications for Use

The ENDOCAM Flex HD Controller has been designed for video endoscopy and can be used for both diagnostic and therapeutic interventions. The camera controller has an HDMI output suitable for connecting an image output device (monitor). This product is designed exclusively for use by specialized medical personnel and may only be applied by medically qualified and adequately trained persons.

The 1-chip HD Camera Head 5521902 is used for diagnostic and therapeutic operations in conjunction with ENDOCAM Flex HD Controller 5521101.
This product is designed exclusively for use by specialized medical personnel and may only be applied by medically qualified and adequately trained persons.

5.3 Substantial Equivalence

The following information summarizes the characteristics of the ENDOCAM® Flex HD Camera System 5521, the 3 CCD HD ENDOCAM® 5550 camera system (K080977), and The Richard Wolf ENDOCAM LOGIC HD Camera System 5525 (K130423).

There are similarities and minor differences in the technological characteristics.

These similarities are:

5.3.1.1 ENDOCAM® Flex HD Camera System 5521

- Have the same Intended Use and field of application.
- Have the same basic design and same / equivalent materials.
- Are used in conjunction with other video equipment and endoscopic accessories.
- Resuable.
- 1-Chip non-autoclavable Camera Head.
- Conforms to Safety Standards IEC 60601-1 and IEC 60601-1-2.

These differences are:

5.3.1.2 ENDOCAM® Flex HD controller 5521101: (K080977)

TV-Standard: The ENDOCAM® Flex HD Controller 5521101 supports the HD standard while the predicate supports the standards PAL and NTSC.

Power consumption [VA]: The ENDOCAM® Flex HD Controller 5521101 has a lower power-consumption than the predicate.

Supply voltage (option): The ENDOCAM® Flex HD Controller 5521101 can be alternatively supplied with 12 VDC Power Supply.

Weight and Dimensions: The ENDOCAM® Flex HD Controller 5521101 has a compact design.

White balance: The ENDOCAM® Flex HD Controller 5521101 supports the white-balance function in a greater Color temperature range.

Input / Output Sockets: The ENDOCAM® Flex HD Controller 5521101 is equipped with USB and HDMI, the predicate is equipped with CAN Interface, HD-SDI Output, DVI Output, and S-Video Output.

These standardized state-of-the-art interfaces are intended for the same purpose (Video Output, Service)

Remote output connectors: The ENDOCAM® Flex HD Controller 5521101 is not equipped with remote outputs to connect a remote control or a recorder / printer.

User interface / GUI: The ENDOCAM® Flex HD Controller 5521101 does not have a graphical user interface (Plug & Play).

5.3.1.3 1-Chip ENDOCAM® Flex HD Camera Head 5521902: (K080977 and K130423)

Locking mechanism: The 1-Chip ENDOCAM® Flex HD Camera Head 5521902 has a C-mount thread for the installation of an objective lens instead of an integrated objective lens with locking mechanism.

Sensor type: The 1-Chip ENDOCAM® Flex HD Camera Head 5521902 is equipped with CMOS Sensors while the predicate devices are equipped with CCD Sensors.

Focal length [mm]: The 1-Chip ENDOCAM® Flex HD Camera Head 5521902 focal length is dependant on the objective lens (coupler).

Length of camera cable: The 1-Chip ENDOCAM® Flex HD Camera Head 5521902 cable is 2.5m instead of 3.0m and 8.0m.

Weight of camera with cable: The 1-Chip ENDOCAM® Flex HD Camera Head 5521902 is lighter than the predicates.

Programmable buttons: The 1-Chip ENDOCAM® Flex HD Camera Head 5521902 is equipped with two buttons with preset functions while the buttons on the Camera Head of the predicate devices are programmable

Dimensions: The 1-Chip Camera Head ENDOCAM® Flex HD Camera Head 5521902 is smaller than the predicate devices.

Endoscopic image adaption and Automatic brightness control: The 1-Chip ENDOCAM® Flex HD Camera Head 5521902 is equipped with an Endoscopic image adaptation while the predicate supports a fully automatic brightness control.

5.3.2 Non-Clinical Testing:

The ENDOCAM® FLEX HD Camera System demonstrates substantial equivalence in safety by tested compliance with:

- IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint): Medical electrical equipment Part 1;
  with differences according to ANSI/AAMI ES60601-1: 2005 / A2:2010:
  General requirements for basic safety and essential performance (3rd edition).
- IEC 60601-2-18:2009 (Third Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition):
  Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment
- IEC 60601-1-6:2010 (Third Edition) + A1:2013 for use in conjunction with IEC 62366:2007 (First Edition) + A1:2014 and IEC 60601-1:2005 (Third Edition) + Corr.1 (2006) + Corr.2 (2007) + A1: 2012 or equivalent consolidated version IEC 60601-1:2012 (Edition 3.1):
  Medical electrical equipment Part 1-6: General requirements for safety - Collateral Standard: Usability

Bench testing of performance specifications were completed and demonstrate that the device met all requirements. Bench comparison testing between the predicate device and the ENDOCAM® Flex HD Camera System demonstrated that the devices are substantially equivalent.

5.3.3 Clinical Testing:

No comparison of clinical performance data was used for demonstration of substantial equivalence.

5.3.4 Conclusion

The ENDOCAM® Flex HD Camera System 5521 has the same intended use and field of application as the predicate devices named in this submission.

Testing has shown that The ENDOCAM® Flex HD Camera System 5521 performs to its technological specifications and operates as intended.

The minor difference in specifications when compared to the predicate 3 CCD HD ENDOCAM® 5550 (K080977) and The Richard Wolf ENDOCAM° Logic HD Camera System 5525 (K130423) does not raise new issues of safety and effectiveness and is substantially equivalent to legally marketed devices