June 28, 2018

Richard Wolf Medical Instruments Corporation
Michael Loiterman
US Head of Regulatory - QA/QC
353 Corporate Woods Parkway
Vernon Hills, IL 60061

Re: K180583
Trade/Device Name: LOGIC 4K CAMERA CONTROLLER
LOGIC 4K CAMERA HEAD
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FET
Dated: May 18, 2018
Received: May 21, 2018

Dear Michael 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Timothy Martin -S
2018.06.28 15:38:28 -04'00'

for
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

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)*
K180583

Device Name
LOGIC 4K CAMERA CONTROLLER
LOGIC 4K CAMERA HEAD

Indications for Use *(Describe)*

LOGIC 4K CAMERA CONTROLLER

The ENDOCAM® Logic 4K Camera System 5525 has been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions. The ENDOCAM® Logic 4K Camera System 5525 is used in conjunction with other video equipment and endoscopic accessories.

LOGIC 4K CAMERA HEAD

Logic 4K Camera Head 85525942 is used for applications in conjunction with the Logic 4K Camera Controller 5525301 for diagnostic and therapeutic interventions.
This product is exclusively intended for use by specialized medical personnel and may only be used by adequately qualified and trained medical doctors.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 5. 510(k) Summary

| **I. Submitter:** | | | Date of Preparation: February 28, 2018 |
|---|---|---|---|
| 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. Michael G. 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 |

| **II. Device (subject device):** | |
|---|---|
| Name of Device: LOGIC 4K CAMERA CONTROLLER<br>LOGIC 4K CAMERA HEAD | Brand Name: ENDOCAM®<br>Model numbers:<br>5525301<br>85525942 |
| Common / Usual name: Endoscopic Video Imaging System | Classification name: Endoscope and Accessories,(21 CFR 876.1500) |
| | Regulatory Class: II |
| | Product Code: FET |

| **III. Predicate device:** | | |
|---|---|---|
| 510(k) Number | Trade or proprietary or model name | Manufacturer |
| K130423 | THE RICHARD WOLF ENDOCAM® LOGIC HD CAMERA SYSTEM 5525 | Richard Wolf Medical Instruments Corporation |
| This predicate has not been subject to a design-related recall. | | |

## 5.1 Description

Richard Wolf's ENDOCAM® Logic 4K Camera System 5525 consists of the Logic 4K Camera Controller and Logic 4K Camera Head. The Logic 4K Camera System has been designed for high-definition video endoscopy and is used in conjunction with other video equipment and endoscopic accessories.

The Logic 4K Camera Controller is the control center of the system, its primary performance characteristics are signal processing of the image data and image recording. The Logic 4K Camera Controller is equipped with various outputs (e.g. HDMI 4K and HDMI HD) and can process a 2K / HD or 4K resolution. The Logic 4K Camera Controller device parameters are controlled and set via the touchscreen, access to all control elements / parameters is possible in OSD via the PC keyboard the handheld remote control or via ***core***.nova.

The Logic 4K Camera Controller housing is made of of powder-coated stainless steel measuring 300mm x 120mm x 416mm; the front foil consists of Polyester AUTOPEX.

The Logic 4K Camera Head is used in conjunction with the Logic 4K Camera Controller, its primary performance characteristic is to receive and transfer an optical image from a variety of endoscopes (rigid, semi-rigid, and flexible endoscopes).

The Logic 4K Camera Head housing is made of stainless steel measuring approximately 40mm x 47mm x 102mm. The camera head cable is securely attached and is 3.0m in length.

The LOGIC 4K Camera Controller and LOGIC 4K Camera Head are not intended to contact the patient directly or indirectly. Therefore, material biocompatibility according to ISO 10993-1 Biological Evaluation of Medical Devices is not required.

The LOGIC 4K Camera Controller and Logic 4K Camera Head are delivered non-sterile. The devices are reusable and do require processing during their use-life. Users are required to process the device for initial use and after each use. Methods of cleaning, disinfection, and sterilization are detailed in the Instruction for Use.

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

### 5.2.1 LOGIC 4K CAMERA CONTROLLER

**Indications for use:**
The ENDOCAM® Logic 4K Camera System 5525 has been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions. The ENDOCAM® Logic 4K Camera System 5525 is used in conjunction with other video equipment and endoscopic accessories.

### 5.2.2 LOGIC 4K CAMERA HEAD

**Indications for use:**
Logic 4K Camera Head 85525942 is used for applications in conjunction with the Logic 4K Camera Controller 5525301 for diagnostic and therapeutic interventions.
This product is exclusively intended for use by specialized medical personnel and may only be used by adequately qualified and trained medical doctors.

## 5.3 Comparison of technological characteristics with the predicate device

The following information summarizes the characteristics of the LOGIC 4K CAMERA products, 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 Similarities

#### 5.3.1.1 LOGIC 4K CAMERA

- Have equivalent Indications for use.
- Have the same basic design and same / equivalent materials.
- Are used in conjunction with other video equipment and endoscopic accessories.
- Reusable.
- Autoclavable Camera Head.
- Conforms to Safety Standards IEC 60601-1 and IEC 60601-1-2.

## 5.3.2 Differences

### 5.3.2.1 LOGIC 4K CAMERA CONTROLLER:

- Power consumption and current rating
- Weight
- Maximum resolution (4K)
- LAN(Ethernet) network connector usage
- Archive format and image compression
- HDMI-4K Output (instead of analog video)
- Removed Interfaces: Video BNC, CAN, S-Video
- Special Imaging Modes (SIM)
- Compatibility with 4K Camera Heads
- Compatiblity to *core*.nova
- Image compression

### 5.3.2.2 LOGIC 4K CAMERA HEAD:

- Imaging Sensor Type
- Weight and dimensions of head with cable
- Reprocessing / Sterilization procedures
- Operating, storage and transport/shipping conditions
- Components and Materials

## 5.3.3 Performance data

The following performance data were provided in support of the substantial equivalence determination.

### 5.3.3.1 Biocompatibility testing

The Logic 4K Camera Controller 5525301 does not contain components that come into direct or indirect contact with patients. Biocompatibility testing per ISO 10993-x does not apply per ISO 10993-1.

The Logic 4K Camera Head 85525942 does not contain components that come into direct or indirect contact with patients. Biocompatibility testing per ISO 10993-x does not apply per ISO 10993-1.

### 5.3.3.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Logic 4K Camera Controller and Logic 4K Camera Head. The ENDOCAM® Logic 4K Camera System 5525 complies 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).
- EN60601-1-2:2015-09 (4th edition) and EN 60601-1-2:2007 §6 / EN 60601-1-2/AC:2010 (3rd edition): Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014); German version EN 60601-1-2:2015
  - Emission:
    - EN 60601-1-2:2015-09 (4th edition) Limit Class: A
    - EN 60601-1-2:2007 §6 / EN 60601-1-2/AC:2010 (3rd edition) Limit Class: A
  - Immunity
    - EN 60601-1-2:2015-09 (4th edition)
    - EN 60601-1-2:2007 §6 / EN 60601-1-2/AC:2010 (3rd edition) Limit Class: A
- 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 (K130423) and the LOGIC 4K CAMERA System demonstrated that the devices are substantially equivalent.

### 5.3.3.3 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern, since failures or latent design flaws are unlikely to cause any injury to the patient or operator.

### 5.3.3.4 Technical data verification

The efficacy and safety of the LOGIC 4K products is documented by the verification / validation testing, which confirms that the products meets all the requirements/ specifications for overall design and electrical safety and that the design inputs and specifications are met.

### 5.3.4 Animal Study

Not applicable, no animal testing was performed.

### 5.3.5 Clinical Studies

Not applicable, clinical studies were not performed.

### 5.3.6 Conclusion

Richard Wolf's ENDOCAM® Logic 4K Camera System 5525 consisting of the Logic 4K Camera Controller and Logic 4K Camera Head have equivalent Indications for Use as the predicate device Richard Wolf ENDOCAM® Logic HD Camera System 5525 cleared with 510(k) K130423.
Safety, EMC, and Performance Testing has shown that the Logic 4K Camera Controller and Logic 4K Camera Head perform as intended and meet their technological specifications.
The minor difference in specifications when compared to the predicate device 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.