June 23, 2020

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

Re: K200617
Trade/Device Name: ENDOCAM Logic 5525 Camera Controller: LOGIC 4K CAMERA CONTROLLER / LOGIC HD CAMERA CONTROLLER / LOGIC HD LITE CAMERA CONTROLLER
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: May 29, 2020
Received: June 2, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Shani P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200617

Device Name
ENDOCAM Logic 5525 Camera Controller: LOGIC 4K CAMERA CONTROLLER / LOGIC HD CAMERA CONTROLLER / LOGIC HD LITE CAMERA CONTROLLER

Indications for Use *(Describe)*
ENDOCAM Logic 5525 Camera Controller:

LOGIC HD CAMERA CONTROLLER / LOGIC 4K CAMERA CONTROLLER:
The Logic HD Camera Controller and the Logic 4K Camera Controller have been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions. The Camera Controllers are used in conjunction with other video equipment and endoscopic accessories.

LOGIC HD LITE CAMERA CONTROLLER:
The Logic HD lite Camera Controller has been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions. The Camera Controller is used in conjunction with other video equipment and endoscopic accessories.

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.

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5 510(k) Summary

I Submitter

Richard Wolf Medical Instruments Corporation
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Vernon Hills, IL 60046

Phone:(847) 913 1113
Fax: (847) 913 0924

Contact Person, Title: Michael Loiterman
Date Prepared: March 6, 2020

Legal Manufacturer

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

II Device

The ENDOCAM Logic 5525 Camera Controller: LOGIC 4K CAMERA CONTROLLER / LOGIC HD CAMERA CONTROLLER / LOGIC HD LITE CAMERA CONTROLLER go under the common name “endoscopic video imaging system”. The following table lists all devices for which clearance is requested:

	Trade name	Model Number(s)	Product classification name	Regulation Number and Name	Product Code	Device Class	Review Panel
ENDOCAM Logic 5525 Camera Controller	LOGIC HD LITE CAMERA CONTROLLER	5525201	Endoscopic Video Imaging System/ Component, Gastroenterology-Urology	876.1500 Endoscope and Accessories	FET	II	Gastro-enterology / Urology
	LOGIC HD CAMERA CONTROLLER	5525101 5525102 5525103 5525104 5525105 5525106 5525107 5525108					
	LOGIC 4K CAMERA CONTROLLER	5525201					

III Predicate Device

Name of Predicate Device: LOGIC 4K CAMERA CONTROLLER (5525301)

510(k) Number: K180583

Regulatory Class: II

Product Code: FET

Manufacturer: Richard Wolf GmbH

The predicate has not been subject to a design-related recall.

5.1 Device Description

5.1.1 Subject Device Identification

	Type number	Description
ENDOCAM Logic 5525 Camera Controller	5525301	LOGIC 4K CAMERA CONTROLLER
	5525101 5525102 5525103 5525104 5525105 5525106 5255107 5525108	LOGIC HD CAMERA CONTROLLER
	5525201	LOGIC HD LITE CAMERA CONTROLLER

ENDOCAM Logic 5525 Camera Controller describes all Richard Wolf ENDOCAM Logic Camera Controllers, by name LOGIC 4K CAMERA CONTROLLER, LOGIC HD CAMERA CONTROLLER and LOGIC HD Lite CAMERA CONTROLLER.

The main purpose of the ENDOCAM Logic 5525 Camera Controller is identifying the applied part(s) and configuring the data stream, managing the interaction and providing an access point for the user.

5.1.2 Subject device characteristics

The ENDOCAM Logic 5525 Camera Controller contains software which is classified as a minor Level of Concern. The main features of the software are configuration of the image processing, archiving and providing different views and a user interface to the user.

The ENDOCAM Logic 5525 Camera Controller is not intended to contact the patient directly or indirectly.

The ENDOCAM Logic 5525 Camera Controller is delivered non-sterile. The devices are reusable and do require cleaning and reprocessing during their use-life, i.e. users are required to clean and disinfect the device before every application and before returning for repairs. Methods of cleaning and reprocessing are detailed in the Instruction for Use.

The ENDOCAM Logic 5525 Camera Controller 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

ENDOCAM Logic 5525 Camera Controller:

LOGIC HD CAMERA CONTROLLER / LOGIC 4K CAMERA CONTROLLER

The Logic HD Camera Controller and the Logic 4K Camera Controller have been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions. The Camera Controllers are used in conjunction with other video equipment and endoscopic accessories.

LOGIC HD LITE CAMERA CONTROLLER

The Logic HD lite Camera Controller has been designed for high-definition video endoscopy and can be used for both diagnostic and therapeutic interventions. The Camera Controller is used in conjunction with other video equipment and endoscopic accessories.

5.3 Comparison of Technological Characteristics with the Predicate Device

The ENDOCAM Logic 5525 Camera Controller has the same intended use as the predicate device. It also has equivalent technical characteristics and design as the predicate device. The operating principle, mechanical design, dimensions and device material are equivalent or the same.

There is only one major difference to the predicate device:

The software version was upgraded from Version 2.0.1 (predicate device) to Version 2.0.8.

5.4 Performance Testing

The same testing that was used for the predicate device to prove performance and functionality was applied to the subject devices.

5.4.1 Software verification and validation

The documentation was prepared for a Minor Level of Concern.

The following Guidance documents were used to prepare the required documentation:

- *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)*
- *Off-The Shelf Software Use in Medical Devices (September 27, 2019)*
- *Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software (January 14, 2005)*
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)*
- *General Principles of Software Validation (January 11, 2002)*
- *Deciding when to submit a 510(k) for a Software Change to an Existing Device (Oct. 25, 2017)*

All changes that were made, including new features, were verified and validated, if needed with the respective application part. It could be shown that these changes do not raise new questions regarding safety or performance and that the ENDOCAM Logic 5525 Camera Controller is substantial equivalent to the LOGIC 4K Camera Controller (predicate device, K180583).

5.4.2 Electromagnetic Compatibility and Electrical Safety

Electromagnetic compatibility testing proved compliance with the following standards for ENDOCAM Logic 5525 Camera Controller

- IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010 + A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-2-18:2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

It could be shown that the changes do not raise new questions regarding safety or performance and that the ENDOCAM Logic 5525 Camera Controller is substantial equivalent to the LOGIC 4K CAMERA CONTROLLER (predicate device K180583).

5.4.3 Performance and Operational testing

The efficacy and safety of Richard Wolf's ENDOCAM Logic 5525 Camera Controller is documented by the verification and validation testing, which confirms that the product meets all the requirements and specifications for overall design, basic safety and essential performance, and that the design inputs and specifications are met.

Functional testing was performed on the ENDOCAM Logic 5525 Camera Controller to prove the performance of the devices.

To demonstrate that the ENDOCAM Logic 5525 Camera Controller is working properly during operation and that functionality is still given after specified storage and transport conditions, testing was performed.

5.4.4 Animal testing

No animal testing was performed on the ENDOCAM Logic 5525 Camera Controller (LOGIC HD LITE, LOGIC HD and LOGIC 4K CAMERA CONTROLLER).

5.4.5 Clinical studies

No clinical studies were performed on the ENDOCAM Logic 5525 Camera Controller (LOGIC HD LITE, LOGIC HD and LOGIC 4K CAMERA CONTROLLER).

5.5 Conclusions

ENDOCAM Logic 5525 Camera Controller (LOGIC HD LITE, LOGIC HD and LOGIC 4K CAMERA CONTROLLER) and their accessories have the same indications for use as the predicate device. The nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as or better than the legally marketed device.

Therefore, the ENDOCAM Logic 5525 Camera Controller has been deemed to be substantially equivalent to the legally marketed device.