October 1, 2021

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

Re: K211332
Trade/Device Name: D Camera Controller
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FET
Dated: August 27, 2021
Received: August 30, 2021

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,

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211332

Device Name
D Camera Controller

Indications for Use *(Describe)*
The D Camera Controller 5522101 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.

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5 510(k) Summary

I Submitter

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Phone:(847) 913 1113
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Contact Person, Title: Michael Loiterman
Date Prepared: August 27, 2021

Legal Manufacturer

Richard Wolf GmbH
Pforzheimer Straße 32
75438 Knittlingen

II Device

The “D Camera Controller” belongs to the ENDOCAM brand. Table 5-1 lists all devices for which clearance is requested.

Table 5-1: Devices for which clearance is requested.

Brand name	Trade name	Model Number	Product classification name	Regulation Number and Name	Product Code	Device Class	Review Panel
ENDOCAM	D Camera Controller	5522101	Endoscopic Video Imaging System / Component, Gastroenterology-Urology	876.1500 Endoscope and Accessories	FET	II	Gastroenterology / Urology

III Predicate Device

Name of Predicate Device: LOGIC HD LITE CAMERA CONTROLLER (5525101)

510(k) Number: K200617

Regulatory Class: II

Product Code: FET

Manufacturer: Richard Wolf GmbH

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

No reference devices were used in this submission.

5.1 Subject Device Description

5.1.1 Device Identification

Table 5-2: Subject device.

Brand name	Type number	Trade name	Package unit
ENDOCAM	5522101	D Camera Controller	1

The D Camera Controller 5522101 has been designed for high-definition video endoscopy and can be used for both, diagnostic and therapeutic interventions.

5.1.2 Device characteristics

Software

The D Camera Controller does contain software.

The software is classified as a moderate Level of Concern.

Materials with patient contact

The D Camera Controller is not intended to contact the patient directly or indirectly.

Single use / reusable

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.

Delivered sterile / non-sterile

The D Camera Controller is delivered non-sterile.

Sterilization method

The D Camera Controller is delivered non-sterile and sterilization is not required.

5.1.3 Environment of Use

The D Camera Controller is intended to be used in professional health care facility environment.

5.1.4 Brief written description of the Device

The subject device is used in combination with sensor endoscopes and a monitor for visualization.

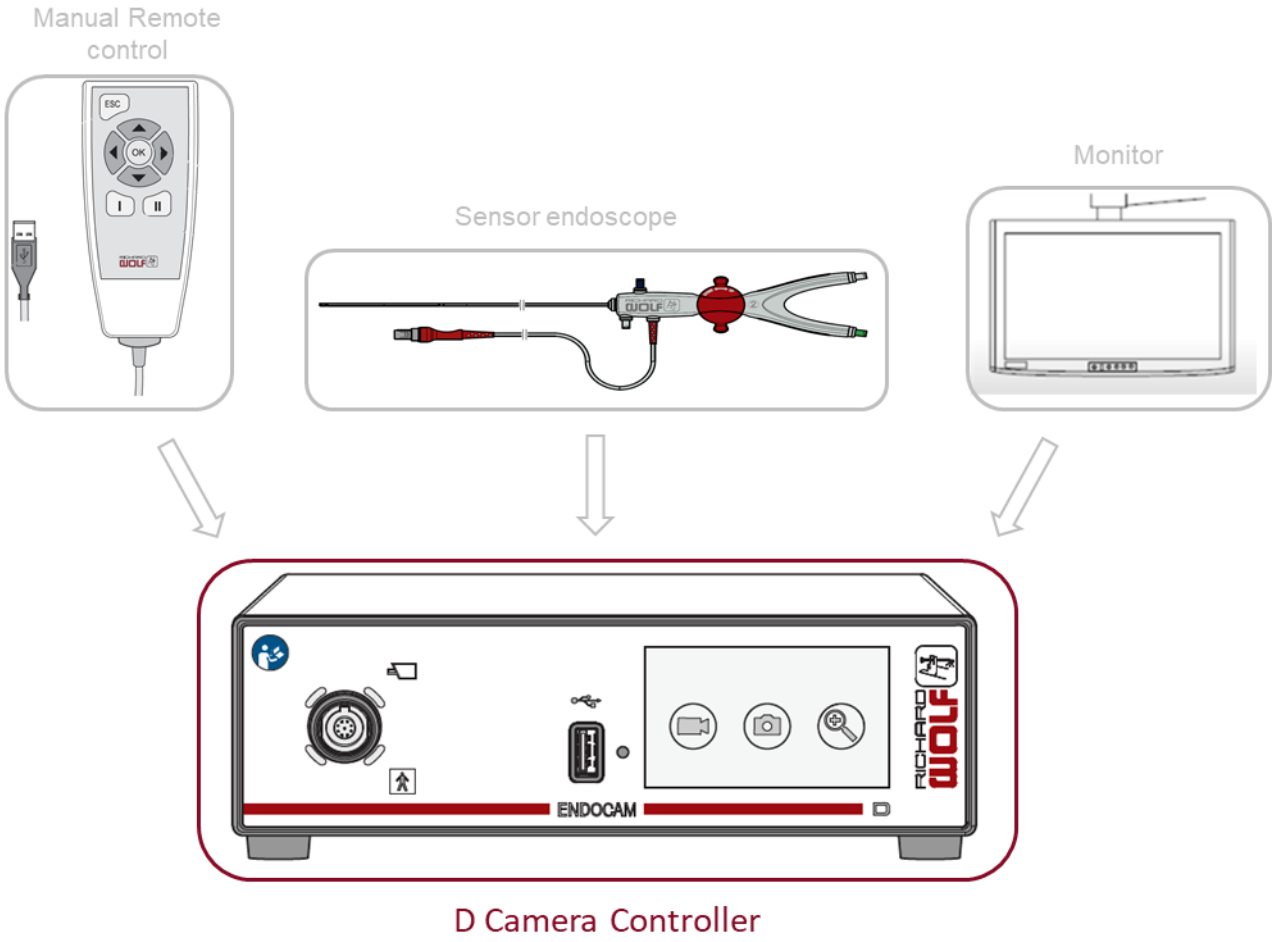

Figure 5-1: Image of the D Camera Controller and its setup possibilities.

In this context, the D Camera Controller is the control unit, its primary performance characteristics are signal processing of the image data and image recording. No further light source is required for the intervention. The D Camera Controller supplies the distal LED of the endoscope with light. The electrical signals provided by the sensor endoscope are processed and adequately converted to render a visible image of the endoscopic scene on a connected display device for the user.

The device features controlled by the software are:

- Sensor Endoscopes (LED light)
- Configuration of Image Processing (zoom)
- Picture Archive and Video Archive
- Temperature Monitoring
- User interface: on-screen display

The product is controlled directly via the control panel on the device front panel. Optionally, a manual remote control (not part of this submission) can be connected to the D Camera Controller via USB ports to control certain functions of the controller. The D Camera Controller must be connected to a 110 V power supply.

5.1.5 Materials of Use

The D Camera Controller consists of a metal housing which does not have any body contact with the patient.

5.1.6 Key Performance Characteristics

The D Camera Controller is the control unit. The subject device processes electrical signals generated by sensor endoscopes and subsequently converts these signals to render a visible image on a connected display. Thus, its primary performance characteristics are signal processing of the image data and image recording.

5.2 Indications for Use

Statement

The D Camera Controller 5522101 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.

User

The D Camera Controller is exclusively intended for use by specialized medical personnel and may only be used by medically qualified and adequately trained persons.

Patient population

The product is intended for adult patients.

The intended patient population is not restricted to ethnics, gender, body height, and weight.

Before use, the doctor in charge must ensure that the product can be safely used in terms of its dimensions or settings.

Explanation on differences to the predicate device

In comparison to the predicate device, the usage of the subject device is further restricted to adults. However, the full indication of use for the subject device is covered by the predicate device and reducing the scope does not lead to new questions regarding safety and effectiveness.

5.3 Comparison of Technological Characteristics with the Predicate Device

5.3.1 Overview Table

Technological characteristics	Subject device	Predicate device
Key Performance characteristics	Signal processing of the image data and image recording	Signal processing of the image data and image recording
Weight	2.3 kg (5.1 lbs)	5.2 kg (11.4 lbs)
Dimensions (W x H x D) [mm]	200 mm x 67 mm x 240 mm	300 mm x 120 mm x 416 mm
Environment of use	Professional health care facility	Professional health care facility
Operating conditions	+10 °C to +40 °C, 20 % to 85 % rel. humidity, atmospheric pressure 700 hPa to 1060 hPa	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa
Materials of use	Metal housing	Metal housing
Materials with patient contact	No	No
Single use / reusable	Reusable	Reusable
Delivered sterile / non-sterile	Non-sterile	Non-sterile
Sterilization method	N/A	N/A
Combinations	Sensor endoscopes	Sensor endoscopes Rigid and flexible endoscopes
	External light source (integrated in distal tip of sensor endoscope) No camera head required	External light source Requires camera head
	Monitor via HDMI (HD + SXGA) and 3G-SDI	Monitor via 2 x HDMI HD
	USB 2.0	USB 2.0
Power consumption [VA] / Current rating [A]	32 / max. 0.32	100 / max. 1.0
Protection class according to EN/IEC 60601-1	I	I
Protection against electric shock	Type BF applied part	Type CF applied part

05 510(k) Summary

Technological characteristics		Subject device	Predicate device
Degree of protection against liquids		IP20	IP20
Cooling method		Constant fan	Controlled fan
Software functions	White balance	Preset with sensor endoscopes	Preset with sensor endoscopes Automatic via button with rigid and flexible endoscopes
	Auto Shutter	Yes	Yes
	Output resolution [pixels]	1280 x 1024 1920 x 1080	1280 x 1024 1920 x 1080 1920 x 1200
	Image formats	JPG	JPEG / TIFF
	Archive formats (video sequence)	AVI	N/A
	Special imaging modes	No	Yes
	“Dialog” function	No, subject device supplies the LED of the distal tip with energy	Yes, enables communication between the camera controller and an interactive light source
	LAN (Ethernet) Network Connector (RJ45)	No (Connection to Core nova system not available)	Yes (Connection to Core nova system, corresponding operator messages/alarms available)

5.3.2 Discussion

The subject device basically shares the technological characteristics of the predicate device. However, there are some improved characteristics and some differences due to technical progress when comparing the subject device with the predicate. These changes had to be verified or validated before claiming substantial equivalence. The changes are categorized as follows:

Main difference

The main difference between the subject devices and the predicate is the change in software and software functions. Several testing activities of the subject device were performed to prove safety and effectiveness. This includes

- Validation of the Software and its functions
- Validation of electromagnetic compatibility and electrical safety
- Validation of the functionality by performance testing bench

Minor differences

The minor differences between the subject devices and the predicate are the change in the technical characteristics such as weight, dimensions, operating conditions, power consumption, cooling method, protection against electric shock, and combination possibilities. To prove that those changed characteristics do not question safety and effectiveness of the subject devices, several performance tests were performed, such as:

- Validation of the electromagnetic compatibility and electrical safety of the devices due to the change in the protection against electric shock, power consumption, and combination possibilities
- Performance testing due to the change in operating conditions, power consumption, cooling method, and combination possibilities
- Packaging validation due to different dimensions and weight

To prove that these differences do not raise any new concerns regarding safety and effectiveness, the following subsections provide an overview of the testing activities and methods performed with the D Camera Controller. For more detail, please check the applicable section.

5.4 Summary of Performance Testing

5.4.1 Non-clinical Performance Testing

5.4.1.1 Biocompatibility

The D Camera Controller does not contain components that come into direct or indirect contact with patients.

Therefore, biocompatibility testing per ISO 10993-X does not apply according to ISO 10993-1.

5.4.1.2 Electromagnetic Compatibility and Electrical Safety

The D Camera Controller includes different hardware components and a different software. Due to this change, electromagnetic compatibility and electrical safety were tested to demonstrate that the changes had no negative influence regarding electromagnetic compatibility and electrical safety. In the following, the applicable standards to which adherence has been demonstrated are listed:

Electromagnetic Compatibility

The devices were tested according to, and compliance was demonstrated with, the following standards:

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

Electrical Safety

The devices were tested according to, and compliance was demonstrated with, the following standards:

EN 60601-1:2005 + A1:2012

IEC 60601-1-6:2010 + A1:2013

IEC 60601-2-18:2009

It could be shown that the subject devices function as safe and as effective as the predicate device and therefore can be deemed substantially equivalent.

5.4.1.3 Performance Testing

The efficacy and safety of Richard Wolf's D 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, essential performance, and that the design inputs and specifications are met.

Due to the above-mentioned differences, testing activities of the D Camera Controller include Packaging, Transportation, Operating conditions, Temperature monitoring, and functionality testing.

The testing performed is equivalent to the testing performed on the predicate device. Therefore, no separate comparison testing was determined to be necessary.

It could be shown that the subject devices met all acceptance criteria and function as safe and as effective as the predicate device and therefore can be deemed substantially equivalent.

5.4.2 Software Verification and Validation Testing

The D Camera Controller is equipped with a new software and therefore its safety and effectiveness must be validated.

Verification and validation testing were performed on the software system and the corresponding software sub-components following the corresponding guidelines:

- 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, 2018, DRAFT)
- General Principles of Software Validation (January 11, 2002)

and IEC 62304 Edition 1.1 2015-06 (Consolidated Version).

In general, the same software tests were concluded for the subject device as for the predicate device. However, due to the subject device's risk class, additional software testing was performed to verify its safety and effectiveness. Therefore, no additional comparison testing was performed.

The software functions of the D Camera Controller are a subset of the software functions of the predicate device. The only additional feature of the D Camera Controller is the video archive function. This difference between the subject device and its predicate does not affect safety or effectiveness as shown by the software testing.

Thus, it could be shown that these changes do not raise new questions regarding safety or performance and that the D Camera Controller is substantial equivalent to the predicate device.

5.5 Clinical Performance Testing

No clinical testing was performed with D Camera Controller.

No animal studies were performed with D Camera Controller.

5.6 Conclusion

The non-clinical data support the safety of the subject device and the verification and validation demonstrate that the D Camera Controller should perform as intended in the specified use conditions. Differences in technological characteristics do not raise any new questions regarding the safety and effectiveness of the D Camera Controller compared to the predicate device.

The data demonstrate that the D Camera Controller performs comparably to the predicate device that is currently marketed for the same intended use.

The D Camera Controller has been deemed to be substantially equivalent to the legally marketed device.