April 30, 2026

KMS Medical Technology Co., Ltd.
Yi Dai
Registration Affairs Specialist
Building A1 and A2, No.769 Qingzhuhu Road, Qingzhuhu
Sub-district, Kaifu
Changsha, Hunan 410201
China

Re: K252858
Trade/Device Name: 4K UHD Endoscopy Camera System (KMS-4K-2088, KMS-4K-2188, KMS-4K-2288)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: September 9, 2025
Received: September 9, 2025

Dear Yi Dai:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha Hithe
Digitally signed by Tanisha Hithe
Date: 2026.04.30 12:49:57 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252858

Please provide the device trade name(s).

4K UHD Endoscopy Camera System (KMS-4K-2088, KMS-4K-2188, KMS-4K-2288)

Please provide your Indications for Use below.

The 4K UHD Endoscopy Camera System, when used in conjunction with optical endoscope, cold light source and monitor, is intended to convert the optical signals captured by the endoscope into electronic signals and transmits them to the monitor for imaging, and can be used for both diagnostic and therapeutic interventions.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary K252858

1. Submitter

Name: KMS Medical Technology Co., Ltd.

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Contact Person: Yi Dai

Position: Registration Affairs Specialist

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Preparation date: April 29, 2026

2. Device

Common Name/Trade Name: 4K UHD Endoscopy Camera System

Model: KMS-4K-2088, KMS-4K-2188, KMS-4K-2288

Regulation Name: Endoscope and accessories

Regulation Number: 21 CFR 876.1500

Regulatory Class: II

Product Code: GCJ

Review Panel: General & Plastic Surgery

3. Predicate Device

	Predicate Device
510(k) Number	K180583
Trade Name	LOGIC 4K CAMERA CONTROLLER, LOGIC 4K CAMERA HEAD
Manufacture	Richard Wolf Medical Instruments Corporation
Regulation Name	Endoscope and accessories
Regulation Number	21 CFR 876.1500
Regulatory Class	II
Product Code	FET
Review Panel	Gastroenterology-Urology Devices

4. Device Description

The 4K UHD (Ultra High Definition) Endoscopy Camera System, when used in conjunction with commercially available optical endoscope, cold light source and monitor, is intended to convert the optical signals captured by the endoscope into electronic signals and transmits them to the monitor for imaging, for using in providing endoscopic video during diagnostic and therapeutic procedures.

The device is reusable for multi-patient use, not intended to contact the patient directly or indirectly, delivered non-sterile, and the camera head must be cleaned and sterilized prior to each use.

The device is intended to be used in professional healthcare facility environment, and exclusively used by specialized medical personnel with medically qualified and adequately trained persons.

The device consists of a Camera Control Unit (CCU) and a Camera Head with an integral cable that connects to CCU and with a detachable coupler that connects to endoscope. The device cannot be connected to network.

The Camera Head is designed to convert the optical signals into electronic signals and transmit them to CCU. The CCU is the control center of the system, designed for processing and recording the images of electronic signals and can process a 4K resolution (3840 × 2160 pixels). The CCU equipped with various inputs/outputs including DVI, 3G-SDI, HDMI, HCOM, USB port.

5. Indications for use

The 4K UHD Endoscopy Camera System, when used in conjunction with optical endoscope, cold light source and monitor, is intended to convert the optical signals captured by the endoscope into electronic signals and transmits them to the monitor for imaging, and can be used for both diagnostic and therapeutic interventions.

6. Comparison of technological characteristics with the predicate devices

Item	Proposed Device	Predicate Device K180583	Remark
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Product Code	GCJ	FET	Gap
Device Class	II	II	Same
Indication for Use	The 4K UHD Endoscopy Camera System, when used in conjunction with optical endoscope, cold light source and monitor, is intended to convert the optical signals captured by the endoscope into electronic signals and transmits them to the monitor for imaging, and can be used for both diagnostic and therapeutic interventions.	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.	Gap
Target population	Adult patients	Adult patients	Same
Anatomical site	Not intended to contact the patient directly or indirectly	Not intended to contact the patient directly or indirectly	Same
Where used	Professional health care facility	Professional health care facility	Same
Prescription/ OTC use	Prescription	Prescription	Same

Item	Proposed Device	Predicate Device K180583	Remark
Principle	Utilize camera head with CMOS image sensor to convert the optical signals captured by endoscope into electronic signals and transmit to control unit. The control unit can process and records image data, and transmit to monitors.	Utilize camera head with CMOS image sensor to convert the optical signals captured by endoscope into electronic signals and transmit to control unit. The control unit can process and records image data, and transmit to monitors.	Same
Software	Control unit contains software; Camera head does not contain software; The software is classified as Basic Documentation Level of concern, since failures or latent design flaws are unlikely to	Camera controller contains software; Camera head does not contain software; The software is classified as Basic Documentation Level of concern, since failures or latent	Same

Item	Proposed Device	Predicate Device K180583	Remark
	cause any injury to the patient or operator.	design flaws are unlikely to cause any injury to the patient or operator.	
Structure and Composition	Camera control unit and Camera head with a detachable coupler	Camera controller and Camera head with a detachable coupler	Same
	1x 1/3 inch CMOS image sensors, aspect ratio 16:9	3x 1/3 inch CMOS image sensors, aspect ratio 16:9	Gap
4K UHD resolution	3840 x 2160px	3840 x 2160px and 4096 x 2160px	Gap
Weight	Control unit: 4.8kg Camera head: 0.15kg	Controller: 6.0kg Camera head: 121g	Gap
Dimensions Control unit (w x h)	346 x 300 x 130 mm	300 x 120 x 416 mm	Gap
Dimensions Touchscreen (w x h)	130*70mm	144 x 78.24 mm	Gap
Materials of use	Metal housing	Metal housing	Same
Materials with patient contact	No	No	Same
Single use / reusable	Reusable for multi-patient use	Reusable for multi-patient use	Same
Delivered sterile / non-sterile	Control unit: Delivered non-sterile; Cannot be sterilized; Camera head: Delivered non-sterile; Require cleaning and sterilization before each use	Controller: Delivered non-sterile; Cannot be sterilized; Camera head: Delivered non-sterile; Require cleaning and sterilization before each use	Same
Operating conditions	+5℃ to +40℃	+10℃ to +40℃	Gap
Combinations	Optical endoscope	Optical endoscope	Same
	External light source	External light source	Same
	Monitors with DVI / 3G-SDI / HDMI interface	Monitors with 3G-SDI / HDMI interface	Gap
	USB2.0, USB3.0 (FAT32/NTFS format))	USB2.0 (FAT32/NTFS format))	Gap
File format of saved pictures / videos	JPEG, BMP (max.3840 x2160） AVI (max.3840 x2160）	JPEG, TIFF (max. 1920 x 1200) MPEG4 (max. 1920 x 1080/60/P)	Gap
LAN (Ethernet) Network Connector usage	No	Yes	Gap
Power supply	Rated voltage: AC100-240V Rated frequency: 50/60 Hz Rated power: 120 VA	Rated voltage: AC100-240V Rated frequency: 50/60 Hz Rated power: 120 VA	Same

Item	Proposed Device	Predicate Device K180583	Remark
Type of protection against electric shock	Class 1	Class 1	Same
Degree of protection against electric shock	CF	CF	Same
Degree of protection against ingress of water	Control unit: IPX0 Camera head: IPX8	Controller: IP20 (not protected) Camera head: IPX7	Gap
Mode of operation	Continuous	Continuous	Same
Cooling method	Constant fan colling	Constant fan colling	Same
Biocompatibility	The device does not contain components that come into direct or indirect contact with patients.	The device does not contain components that come into direct or indirect contact with patients.	Same
Performance Standards	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-6	IEC 60601-1 IEC 60601-2-18 IEC 60601-1-6	Same
	IEC 60601-1-2 IEC 60601-4-2	IEC 60601-1-2 IEC 60601-4-2	Same
Focal length	14-32mm	13-29mm	Gap
Minimum illumination	≤1 Lux / F1.6	< 0.7 Lux / F1.8 @ 50% Level	Gap
Signal to noise ratio (SINR)	56dB	52 dB	Gap

The proposed and predicate device have equivalent Indications for use.

The proposed and predicate device have the same structure and composition.

The proposed and predicate device have different technological characteristics, and these differences do not raise different questions of safety and effectiveness.

7. Non-Clinical Testing

Performance testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards

- IEC60601-1 Edition3.2 2020-08 CONSOLIDATED VERSION Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance.
- IEC60601-2-18 Edition3.0 2009-08 Medical electrical equipment Part 2-18:

Particular requirements for the basic safety and essential performance of endoscopic equipment.

- IEC 60601-1-6 Edition3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance Collateral standard: Usability.
- IEC 60601-1-2 Edition4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic disturbances Requirements and tests.
- IEC TS 60601-4-2 Edition 1.0 2024-03 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

Biocompatibility

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.

Cleaning validation：

The cleaning validation demonstrates that no visible soil was seen on the processed devices under normal lighting conditions after cleaning. The cleaning method is acceptable.

The cleaning validation is Reference AAMI ST98:2022 Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices.

Sterilization validation：

The sterilization validation demonstrates that the sterilization method was effective on the test device and achieve a SAL of 10^{-6}.

The sterilization validation is reference ISO17664-1: 2021 Processing of health care

products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices.

Repeated cleaning + sterilization tolerance validation:

After 50 repeated washes and low-temperature hydrogen peroxide plasma sterilization, no abnormalities were observed in the visible parts of the three samples of the instruments, and the device still conforms to product standards.

8. Clinical Testing

None

9. Conclusion

The 4K UHD Endoscopy Camera System is substantially equivalent to the predicate device. The non-clinical testing demonstrates that the device is as safe and effective as the predicate device.