August 21, 2020

Scivita Medical Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co, Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K200216
Trade/Device Name: 4K UHD Camera System
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope and Accessories
Regulatory Class: II
Product Code: HET, EOB, FGB, GCJ, NWB, FET, HRX
Dated: July 9, 2020
Received: July 22, 2020

Dear Diana Hong:

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,

Jason R. Roberts, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200216

Device Name
4K UHD Camera System

Indications for Use *(Describe)*
4K UHD Camera System is used to provide imaging of the operative area in endoscopic surgery.

4K Camera Control Unit
The 4K camera control unit has been designed to be used with endoscopes, 4K camera head, light source, monitors, and other ancillary equipment for endoscopic diagnosis, treatment, and observation. The 4K camera head is compatible with the 4K camera control unit only.

4K Camera Head
The 4K camera head has been designed to be used with endoscopes, 4K camera control unit, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.

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.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements per 21 CFR 807.92.

1. Sponsor Identification

Sponsor Identification:

Scivita Medical Technology Co., Ltd.
No.8, Zhong Tian Xiang, Suzhou Industrial Park, Suzhou, Jiangsu, 215000, China.

Establishment Registration Number: Not yet registered

Contact Person: Ruqin Wu
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Designated Submission Correspondent:
Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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Tel: +86-21-22815850,
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Email: info@mid-link.net

Date of Preparation: August 20, 2020

2. Device Information

Trade Name: 4K UHD Camera System
Common Name: Endoscopic Video Imaging System
Model: ES-CS4K100/100C
ES-CS4K200/100C
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic Laparoscope And Accessories
Regulatory Class: II
Product Code: HET, EOB, FGB, GCJ, NWB, FET, HRX

3. Identification of Predicate Device

510(k) Number: K151011
Product Name: Olympus Medical Systems Corp.
The predicate device has not been subject to a design-related recall.

4. Device Description

The proposed system, 4K UHD Camera System, comprises the 4K camera control unit, 4K camera head, objective lens and power cable and video cables. The proposed system is reusable device, and provided non-sterile. The proposed camera head and should be cleaned and disinfected after each use.

The video cables include an SDI video cable and an HDMI video cable. The 4K camera control unit has two models (ES-CS4K100 and ES-CS4K200) with the only difference on signal output terminals, the detail difference refers to Table 3 of this document; the 4K camera head only has one model (ES-CS4K100C). Therefore, the 4K UHD Camera System is available in two models in combination of the 4K camera control unit and 4K camera head. The system model and primary components of the proposed system are provided in Table 1.

Table 1 System model and primary component

4K UHD Camera System	System model	Primary component
	ES-CS4K100/100C	4K camera control unit (ES-CS4K100)
		4K camera head (ES-CS4K100C)
	ES-CS4K200/100C	4K camera control unit (ES-CS4K200)
		4K camera head (ES-CS4K100C)

Working Principle and/or Mechanism of Action:
The 4K UHD Camera System can provide 4K images and/or 2K images via different signal output terminals. The 4K camera head incorporates a complementary metal oxide semiconductor (CMOS) image sensor to convert optical images into electronical signals. The objective lens on end of the 4K camera head is used to connect the camera head with the endoscope.

The 4K UHD Camera System is designed to be used with endoscopes, a light source (ES-LS110D), monitors, light guide cables and other ancillary equipment for endoscopic diagnosis, treatment and observation.

Conditions of Use:
4K UHD Camera System is intended to be used in hospitals, clinics and doctor's office by doctors and trained healthcare professionals. Compatible equipment of the proposed system is provided in the Table 2.

Table 2 Recommended compatible equipment of the proposed system

Equipment	Manufacturer	Model	K Number
4K UHD Camera System	SCIVITA	ES-CS4K 100/100C	This application
HSV LAPAROSCOPY SET (optional select one from all endoscope when connecting with the proposed device to test)	WOLF	Laparoscope (0°, 30°,45°)	K941541
HENKE SASS WOLF OF AMERICA ARTHROSCOPE	WOLF	Arthroscope (0°,30°,70°)	K080560
SINUSCOPE AND ACCESSORIES	WOLF	Sinuscope (0°,30°,70°)	K981751
LED LIGHT SOURCE	SCIVITA	ES-LS110D	
Monitor	SONY	LMD-X2705MD/ LMD-X550MD/ LMD-X310MD/ LMD-X310MT	K150377

The key performance specifications of the proposed system are provided in the Table 3.

Table 3 General specifications

Weight		5Kg
Dimension(W×H×D)		370 (W) ×95 (H)×425.5(D) mm
Camera Head		1/3" Three Chip CMOS
Signal output (resolution)		4096×2160, 1920×1080
Signal output (interface type)	ES-CS4K100/100C	There are HDMI×2, SDI-1 BNC terminal×4, SDI-2 BNC terminal×1 seven interfaces in total. This model can output the following three types: 4K SDI × 1, 2K SDI × 1, 4K HDMI × 2
	ES-CS4K200/100C	There are HDMI×2, SDI-1 BNC terminal×4, SDI-2 BNC terminal×1 seven interfaces in total. This model can

		output the following four types: 4K SDI × 1, 2K SDI × 1, 4K HDMI × 1, 2K HDMI × 1
Video output format		HDMI output: 2160/59.94p, 2160/50p, 1080/59.94p, 1080/59.94i, 1080/50p, 1080/50i SDI output: 2160/59.94p, 2160/50p, 1080/59.94p, 1080/59.94i, 1080/50p, 1080/50i
Image recording		The data is stored in real time to the external access USB interface device by photographing or recording functions.
Operation mode		Continuous operation
White balance		Automatic white balance

The level of concern of the software contained in the subject device is determined to be Moderate Level of Concern.

5. Indications for use:

4K UHD Camera System is used to provide imaging of the operative area in endoscopic surgery.
4K Camera Control Unit
The 4K camera control unit has been designed to be used with endoscopes, 4K camera head, light source, monitors, and other ancillary equipment for endoscopic diagnosis, treatment, and observation. The 4K camera head is compatible with the 4K camera control unit only.

4K Camera Head
The 4K camera head has been designed to be used with endoscopes, 4K camera control unit, and other ancillary equipment for endoscopic diagnosis, treatment, and observation

The indications for use statement of the subject device is similar to that of the video processor component of the predicate device. The main difference in the indication for use is the subject device doesn't include indications for the light source because a light source is not included in this subject device submission. The indications for use of the camera control unit and camera head of the subject device and predicate device are the same. The differences in the indications do not represent a new intended use.

6. Comparison of Technological Characteristics

Table 4 General Comparison

ITEM	Subject Device K200216	Predicate Device K151011
Name	4K UHD Camera System	VISERA 4K UHD SYSTEM
Product Code	HET, EOB, FGB, GCJ, NWB, FET, HRX	HET, GCJ, EOB, EOQ, FGB, NWB
Regulation Number	21 CFR 884.1720	21 CFR 884.1720,
Class	II	II
Indications for Use	4K UHD Camera System is used to provide imaging of the operative area in endoscopic surgery. 4K Camera Control Unit The 4K camera control unit has been designed to be used with endoscopes, 4K camera head, light source, monitors, and other ancillary equipment for endoscopic diagnosis, treatment, and observation. The 4K camera head is compatible with the 4K camera control unit only. 4K Camera Head The 4K camera head has been designed to be used with endoscopes, 4K camera control unit, and other ancillary equipment for endoscopic diagnosis, treatment, and observation	VISERA 4K UHD CAMERA CONTROL UNIT OLYMPUS OTV-S400 The camera control unit has been designed to be used with Olympus endoscopes, camera heads, light source, monitors, and other ancillary equipment for endoscopic diagnosis, treatment, and observation. VISERA 4K UHD XENON LIGHT SOURCE OLYMPUS CLV-S400 The light source has been designed to be used with Olympus endoscopes, camera control unit, light guide cables, and other ancillary equipment for endoscopic diagnosis, treatment, and observation. 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB The camera head has been designed to be used with Olympus endoscopes, camera control unit, and other ancillary equipment for endoscopic diagnosis, treatment, and observation.
Single use / Reusable	Reusable	Reusable
Sterile	No	No
Configuration (primary components)		light source
	4K Camera Control Unit	4K Camera Control Unit
	4K Camera Head	4K Camera Head

Table 5 Comparison of ES-CS4K100/200 Camera Control Unit

ITEM		Subject Device K200216	Predicate device K151011
Model		ES-CS4K100 ES-CS4K200	VISERA 4K UHD CAMERA CONTROL UNIT OLYMPUS OTV-S400
Power supply		100-240V AC, 50/60Hz	100-240V~ ±10%, 50/60Hz±1Hz
Dimension		370(W) ×95(H)×425.5(D) mm	390(W） × 160(H) × 506(D) mm
Weight		5Kg	13.5Kg
Input power		150VA	350VA
Resolution		4096×2160pxl, 1920×1080pxl	4096×2160, 3840×2160, 1920×1080
Image signal output	ES-CS4K100	Total seven signal output terminals HDMI (4K HMDI) ×2, SDI (4K SDI) terminal×4, SDI (3G/HD-SDI) terminal×1; The seven signal output terminals can output three types of signal output: 4K SDI , 2K SDI , 4K HDMI	SDI（3G/HD）
	ES-CS4K200	Total seven signal output terminals: HDMI (4K HMDI) ×1, HDMI (HMDI)×1, SDI (4K) terminal×4, SDI (3G/HD-SDI) terminal×1; The seven signal output terminals can output four types of signal output: 4K SDI , 2K SDI , 4K HDMI, 2K HDMI	
Standard Color Chart Output		Color bar image	Color bar image
Observation light imaging		White light imaging(WLI) Six imaging function	White light imaging (WLI) Narrow band imaging (NBI)

Table 6 Comparison of Camera Head

ITEM	Subject Device K200216	Predicate Device K151011
Model	ES-CS4K100C	4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB
Camera Head dimension	W48 mm × H64 mm × L168 mm	W43.6 mm × H49.5 mm × L122.5 mm
Cable dimension	φ5mm× 2.9m	5.1 mm × 3 m

Wight(excluding cable)	231.4g (excluding cable)	280 g (excluding cable)
Reprocessing	End user reprocess Disinfection by using glutaraldehyde solution	End user sterilized EOG/ STERRAD

The differences in technological characteristics do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Performance Testing

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

- IEC 60601-1:2005+AMD1:2012 Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014, Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic compatibility- 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
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems.
- AAMI TIR 30:2016 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- AAMI TIR 12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers

The software of the proposed device was validated as Moderate level of concern (LoC) in accordance with the following guidance documents: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff

The following performance testing were also conducted on the subject device and the subject device met all predefined acceptance criteria:

- Depth of Field Test
- Resolution Test
- Direction of View and Field of View Test
- Color Reproduction and Signal Noise Ratio Test
- Geometric Distortion Test
- Image Frame Frequency and System Delay
- Image Intensity Uniformity

8. Conclusion

The performance testing summarized above support a substantial equivalence determination. The performance testing demonstrate that the subject device is as safe and as effective as the legally marketed predicate device.