October 2, 2025

Shenzhen Sophway Technology Co., Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
China

Re: K250551
Trade/Device Name: 4K Endoscopic Camera System (SV-800, SV-800I, SV-800R, SV-800N)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ, EOB, EOQ, FGB, HET, NWB
Dated: September 2, 2025
Received: September 2, 2025

Dear Eva Li:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2025.10.02 09:43:26 -04'00'

Colin Kejing Chen
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250551

Device Name

4K Endoscopic Camera System (SV-800, SV-800I, SV-800R, SV-800N)

Indications for Use *(Describe)*

It is used to connect with an optical endoscope during the endoscopic diagnosis, treatment, and observation. And to capture, process and transmit images in the human body cavity under the field of view observed by the endoscope to the monitor.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(K) Summary

1. General Information

Applicant:	Shenzhen Sophway Technology Co.,Ltd.
Address	7th Floor, Building 9#, Zhongyuntai Technology Industrial Park, Songbai Rd., Shiyan Avenue, Bao'an, Shenzhen, 518108 Guangdong, P.R. China
Contact:	Shuting Chen
Tel	+86 755 36368352
Date of preparation:	September 30，2025
Device Identification:	
Common Name:	4K Endoscopic Camera System
Trade Name:	Gynecologic laparoscope and accessories
Device Classification:	Class II
Regulation	21 CFR 884.1720
Product Code	HET, EOB, EOQ, FGB, GCJ, NWB

2. Predicate device

K151011
VISERA 4K UHD SYSTEM
Olympus Medical Systems Corp.

3. Indication for Use

It is used to connect with an optical endoscope during the endoscopic diagnosis, treatment, and observation. And to capture, process and transmit images in the human body cavity under the field of view observed by the endoscope to the monitor.

4. Device Description

The 4K Endoscopic Camera System consists of a camera control unit and a 4K camera head.

The device is intended to be used to connect with an optical endoscope during the endoscopic diagnosis and/or treatment/surgery, and to capture, process and transmit images in the human body cavity under the field of view observed by the endoscope to the monitor.

There are 4 models of the device. The hardware configuration of the device of 4 models are same, and difference is different functions which opened up through software.

5. Technology comparison with the predicate device

	Subject device	Predicate device	Comparison
Device name	4K Endoscopic Camera System	VISERA 4K UHD CAMERA CONTROL UNIT OLYMPUS OTV-S400 4K CAMERA HEAD OLYMPUS CH-S400-XZ-EB	NA
Device code	HET, EOB, EOQ, FGB, GCJ, NWB	HET, EOB, EOQ, FGB, GCJ, NWB	Same
Indication for use	It is used to connect with an optical endoscope during the endoscopic diagnosis, treatment, and observation. And to capture, process and transmit images in the human body cavity under the field of view observed by the endoscope to the monitor.	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. 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.	Similar1
electrical safety	Comply to IEC 60601-1:2020, IEC 60601-2-18: 2009	Comply to IEC 60601-1: 2005+A1,IEC 60601-2-18: 2009	same
EMC	Comply to IEC IEC60601-1-2:2021	Comply to IEC IEC60601-1-2:2007	same
CCU			
Dimension	364(L)*325(W)*137(H)mm	390(W）× 160(H) × 506(D) mm	similar
Resolution	4K（3840×2160） （1920×1080）	4K（4096pxl×2160pxl）	similar
Signal output (interface type)	12G SDI × 1, 3G SDI × 1, HDMI × 2	SDI（3G/HD）	Different1
Video output format	3840×2160, 1920×1080	4096x2160，3840x2160，or 1920x1080	similar
Image recording	The data is stored in real time to the external access USB interface device or internal hard disk by photographing or recording functions.	No	Different2

Operation mode	Continuous operation	Continuous operation	same
White balance	Automatic white balance	Automatic white balance	same
Observation light imaging	White light imaging(WLI)	White light imaging(WLI)	same
details about the display	Touchscreen	Touchscreen	same
input/output (signals, power)	70VA	350VA	Different3
Operating temperature	10~30℃	10~35℃	Different4
Operating humidity	30% ~ 85%RH	30 ~ 85% RH	Same
Operating atmosphere	700~1060（hpa）	700 ~ 1060 hPa	Same
Power Supply	100-240V 50/60Hz	100-240V 50/60Hz	same
Weight	4.8Kg	13.5Kg	Similar
Camera head			
image resolution	1/3” Three Chip CMOS： 1920×1080/CMOS	Undisclosed	N/A
number of pixels	1/3” Three Chip CMOS： 1920×1080/CMOS	Undisclosed	N/A
Size	W51 mm × H48 mm × L101 mm	W43.6 mm × H49.5 mm × L122.5 mm	similar
Weight	570 kg	280 g	similar
Operating temperature	10~30℃	10~35℃	similar
Operating humidity	30% ~ 85%RH	30 ~ 85% RH	Same
Operating atmosphere	700~1060 hpa	700 ~ 1060 hPa	Same
size of pixels	2.9um	Undisclosed	N/A
size of active area	1/3"	Undisclosed	N/A
focal length	14mm	23.5mm	similar
focus control details	Automatic; Manual	Automatic; Manual	same
image sensor	CMOS image sensor	CMOS image sensor	same
Single use or reuse	reuse	reuse	same
Reprocessing	End user sterilized ASP Sterrad 100NX plasma sterilizer	End user sterilized EOG/ STERRAD	similar

6. Non-Clinical performance tests:

The differences of technological characteristics between the predicate device and the subject device are confirmed that they are substantially equivalent through the following tests and standards.

- A performance testing were conducted to demonstrate that the 4K Endoscopic Camera System performs according to specifications and functions as intended. Tests results obtained verified the safety and effectiveness of the devices in accordance with design specifications and applicable standards.
- The instructions for reprocessing of the subject devices include Cleaning, Disinfection, and Sterilization. All cleaning, disinfection, and sterilization methods have been validated.
- The software validation activities were performed in accordance with the FDA Guidance, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”
- The cybersecurity validation activities were performed in accordance with the FDA Guidance, “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”
- Electromagnetic compatibility, electric safety, and thermal safety had been confirmed.
- Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2019. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

The following voluntary standards to comply with have been applied to the 4K Endoscopic Camera System:
IEC 60601-1: 2020,
IEC 60601-1-2: 2021,
IEC 60601-2-18: 2009,

7. Conclusion

The subject device is substantially equivalent to its predicate devices. The nonclinical testing demonstrates that the device is as safe, as effective as well as the legally marketed devices under K151011.