July 1, 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: K250204
Trade/Device Name: Endoscopic Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FET
Dated: June 20, 2025
Received: June 20, 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,

James H. Jang -S

Digitally signed by James H. Jang -S
Date: 2025.07.01 22:11:06 -04'00'

James Jang, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250204

Device Name
Endoscopic Camera System

Indications for Use *(Describe)*
Endoscopic Camera System is a camera control unit (CCU) for use with camera heads and video endoscopes for visualization, image recording and documentation during general endoscopic and microscopic procedures.

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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510(K) Summary

1. General Information

Applicant:	Shenzhen Sophway Technology Co.,Ltd.
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Submitter:	Eva Li
Address:	Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel No. :	008618101897399
Date of preparation:	June 30, 2025

Device Identification:	
Common Name:	Endoscopic Video Imaging System/Component
Trade Name:	Endoscopic Camera System
Device Classification:	Class II
Regulation	21 CFR 876.1500
Product Code	FET

2. Indication for Use

Endoscopic Camera System is a camera control unit (CCU) for use with camera heads and video endoscopes for visualization, image recording and documentation during general endoscopic and microscopic procedures.

3. Device Description

The device consists of a camera control unit (CCU) and a 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.

4. Technology

Predicate Device: Product Code FET, Image1 SPIES System, cleared under K160044

The predicate and subject devices are both camera systems used for the visualization and documentation of endoscopic and microscopic procedures. They have the same operational principals and indications for use.
The subject device and the predicate devices have some minor technology differences: Horizontal resolution, Spatial frequency response, Field of view, Focal length, Dimensions, Weight of camera head, Image delay, Video output, USB port of CCU.
The bench test data for the Endoscopic Camera System demonstrates that the design characteristics used as the basis for the comparison have been met. The results show that the subject device has met all its specifications. The performance validation test report can be provided upon request. The minor difference in specifications when compared to the predicate device under K160044, does not raise new issues of safety and effectiveness and the devices are substantially equivalent for the visualization and documentation of endoscopic and microscopic procedures.

5. Non-Clinical performance tests:

The Endoscopic Camera System undergone bench testing for performance verification and validation purposes.

- Electrical safety testing according to IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION
- EMC testing according 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
- Reprocessing validation according to AAMI TIR 12:2020, Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A guide for Device Manufactures
- Service Life Evaluation
- Software Verification Tests according to the Guidance of Content of Premarket Submissions for Device Software Functions
- Bench performance for camera, CCU and system level function tests.

The bench testing performed verified and validated that the Endoscopic Camera System has met all its design specification and is substantially equivalent to the predicate device, Image1 SPIES System.

6. 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 K160044.