October 22, 2024

Shanghai SeeGen Photoelectric Technology Co., Ltd.
Yihua Ma
RA Supervisor
3 Floor, Building No.1, 4299 JinDu Road,
Minhang District
Shanghai, 201108
CHINA

Re: K241532
Trade/Device Name: Flexible Video-Choledo-Cysto-Ureteroscope System (PL-2100)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET, KQM
Received: September 11, 2024

Dear Yihua Ma:

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,

Mark R. Kreitz -S

for 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241532

Device Name

Flexible Video-Choledo-Cysto-Ureteroscope System (PL-2100)

Indications for Use *(Describe)*

The Flexible Video-Choledo-Cysto-Ureteroscope System is indicated for endoscopic examination in the urinary tract and can be used percutaneously to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures. The Flexible Video-Choledo-Cysto-Ureteroscope System is also indicated for the examination of bile ducts surgically, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1 Submitter

Submitted by:	Shanghai SeeGen Photoelectric Technology Co., Ltd. Address: 3 Floor, Building No.1, 4299 JinDu Road, Minhang District, Shanghai, China
Contact Person:	Yihua Ma RA Supervisor Shanghai SeeGen Photoelectric Technology Co., Ltd. Address: 3 Floor, Building No.1, 4299 JinDu Road, Minhang District, Shanghai, China Phone: 0086-18616909737 Email: mayihua@seegen.com.cn
Date Prepared:	May 30, 2024

5.2 Device

Device Name:	Flexible Video-Choledo-Cysto-Ureteroscope System
Common Name:	Choledochoscope and Accessories, Flexible/Rigid; Camera, Surgical and Accessories
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Classification Name：	Endoscopic Video Imaging System/Component, GU
Product Code:	KQM,FET

5.3 Predicate Device

Device Name:	Flexible Video-Choledo-Cysto-Ureteroscope System, K211686
Common Name:	Choledochoscope and Accessories, Flexible/Rigid; Camera, Surgical and Accessories; LED light Source
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	FGB, FBN, FET, FAJ, FGA

5.4 Device Description

Imaging Processor System (Including Light Source) is composed of lighting system, image processing board. The lighting system provides the light source for the endoscope probe at the back end. The image processing board receives electronic signals from the front-end camera module and processes them, and finally transmits them to the display through the video interface. Flexible Video-Choledo-Cysto-Ureteroscope is a kind of medical electronic optical instrument, also known as optical camera, which can enter into the human bladder, ureter, biliary and pancreatic duct for observation and diagnosis. The operator delivers the optical camera system to the site of diagnosis and treatment by means of a mechanical part with a flexible insertion tube and a system of bends. The product is equipped with tiny size digital imaging parts --photoelectric sensors “CMOS”, on which the objects in human cavity will be transferred though lens optical system, and converts light signals into electrical signals. The electrical signal will be transferred to Imaging Processor System (Including Light Source) and display images on it's monitor output for doctor observation and diagnosis.

5.5 Indication for Use:

The Flexible Video-Choledo-Cysto-Ureteroscope System is indicated for endoscopic examination in the urinary tract and can be used percutaneously to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures. The Flexible Video-Choledo-Cysto-Ureteroscope System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy.

5.6 Substantial Equivalence and Technological Characteristics

Item	Imaging Processor System(Including Light Source) (Proposed Device)，Model:PL-2100	Imaging Processor System(Including Light Source), K211686(Primary Predicate Device)，Model:PL-1000	Comment
Indication for Use	Signals from the endoscope are converted to the image and displayed on an inspection monitor.	Signals from the endoscope are converted to the image and displayed on an inspection monitor.	Same
Target patients:	Patients who are considered suitable for the application of this product by the physician	Patients who are considered suitable for the application of this product by the physician	Same
User qualifications	Physicians (experts who have been approved by the endoscopic medical safety administrator at each medical facility. If the eligibility requirements are defined by an official body such as a government entity and/or an academic society, follow such requirements.) Specific training to use this product is not required.	Physicians (experts who have been approved by the endoscopic medical safety administrator at each medical facility. If the eligibility requirements are defined by an official body such as a government entity and/or an academic society, follow such requirements.) Specific training to use this product is not required.	Same
Place of use	Medical facility	Medical facility	Same
Power input	100–240V~50/60Hz48VA	100–240V~50/60Hz45VA	Similar
Imaging output	CVBS&DVI&S-VIDEO	HDMI	Different
Light Source	LED 2W	LED 2W	Same
Lamp Life	30,000 hrs	30,000 hrs	Same
Screen	10.1 inches	N/A	Different
USB Flash Memory	USB 2.0(Max:128G;FAT32)	USB 2.0(Max:128G;FAT32)	Same

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Substantial Equivalence Discussion

illuminatio n	≥2000LUX	≥2000LUX	Same
Resolution	d = 10mm, the MTF50 value of the SFR at the center part shall not be lower than 200lw / pH, and the MTF50 value at 70% of the field of view position shall not be lower than the MTF50 value at 80% of the center position.	d = 10mm, the MTF50 value of the SFR at the center part shall not be lower than 200lw / pH, and the MTF50 value at 70% of the field of view position shall not be lower than the MTF50 value at 80% of the center position.	Same
Filed of View	110°±10%	110°±10%	Same
Observe the depth of field	5-50mm MTF50 ≥ 200 (LW / PH)	5-50mm MTF50 ≥ 200 (LW / PH)	Same
Direction of View	0°±2°	0°±2°	Same
TV distortion	＜|15%|	＜|15%|	Same
SNR and Dynamic Range	SNR≥10 DR≥90	SNR≥10 DR≥90	Same
Color reducibilit y test	ΔE≤23 ΔC≤23	ΔE≤23 ΔC≤23	Same
Shading	Lightness non-uniformity D_L≥70 Luminance non-uniformity D_Y≥95	Lightness non-uniformity D_L≥70 Luminance non-uniformity D_Y≥95	Same

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5.7 Substantial Equivalence

The new image processor,(PL-2100), are used as predicate device compared to proposed device Flexible Video-Choledochoscope System manufactured by Shanghai SeeGen Photoelectric Technology Co., Ltd.

5.8 Non-clinical Performance Data

The Flexible Video-Choledo-Cysto-Ureteroscope System has been successfully tested for its functions. Safety testing was performed including electrical safety IEC 60601-1 and IEC 60601-2-18, electromagnetic compatibility per IEC 60601-1-2 and biocompatibility of the patient contact materials per ISO 10993. Additional validations were conducted for the sterilization process, EO residual, transportation and Photobiological safety, optical and colour performance test.

5.9 Clinical Test Data

No Clinical Study is included in this submission.

5.10 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Shanghai SeeGen Photoelectric Technology Co., Ltd. has demonstrated that proposed device Flexible Video-Choledo-Cysto-Ureteroscope System is substantially equivalent to Boston Scientific Corporation's currently marketed Flexible Video-Choledo-Cysto-Ureteroscope System, K211686.