March 7, 2025

Shanghai SeeGen Photoelectric Technology Co., Ltd.
Die Li
RA specialist
3 Floor, Building No.1, 4299 JinDu Road Minhang District
Shanghai, China 201108
China

Re: K243535
Trade/Device Name: Flexible Video-Choledochoscope (CHV-110J-U); Flexible Video-Choledochoscope (CHV-US120J-U)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBN
Dated: February 7, 2025
Received: February 7, 2025

Dear Die 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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant 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)*

K243535

Device Name

Flexible Video-Choledochoscope (CHV-110J-U);
Flexible Video-Choledochoscope (CHV-US120J-U)

Indications for Use *(Describe)*

The Flexible Video-Choledochoscope is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

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:	Die Li RA Supervisor Shanghai SeeGen Photoelectric Technology Co., Ltd. Address: 3 Floor, Building No.1, 4299 JinDu Road, Minhang District, Shanghai, China Phone: 0086-18721292535 Email: lidie@seegen.com.cn
Date Prepared:	Oct 10, 2024

5.2 Device

Device Name:	Flexible Video-Choledochoscope
Common Name:	Choledochoscope and Accessories, Flexible/Rigid; Camera, Surgical and Accessories;
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	FBN, KQM

5.3 Predicate Device

Device Name:	Flexible Video-Choledochoscope System, K222261
Common Name:	Choledochoscope and Accessories, Flexible/Rigid; Camera, Surgical and Accessories;
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	FBN, KQM, NTN, FET

5.4 Device Description

Flexible Video-Choledochoscope is a kind of medical electronic optical instrument, also known as optical camera, which can enter into the human 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.

This device must be used with a duodenoscope.

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 its monitor output for doctor observation and diagnosis.

5.5 Indication for Use:

The Flexible Video-Choledochoscope is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

5.6 Substantial Equivalence and Technological Characteristics

Item	Flexible Video-Choledochoscope (Proposed Device) The following type: For Flexible Video-Choledochoscope: CHV-110J-U/CHV-US120J-U	Flexible Video-Choledochoscope System (Predicate Device),K222261 The following type: For Flexible Video-Choledochoscope: CHV-US100J-U/CHV-US110J-U	Comment
Indication for Use	The Flexible Video-Choledochoscope is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico - biliary system including the hepatic ducts.	The Flexible Video-Choledochoscope is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico - biliary system including the hepatic ducts.	Same
Imaging Technology	CMOS chips at distal end	CMOS chips at distal end	Same
Illumination Source	LED	LED	Same
Distal End(mm) Outer Diameter	CHV-110J-U (OD:3.8mm) CHV-US120J-U (OD:2.6mm)	CHV-US100J-U (OD:3.3mm) CHV-US110J-U (OD:3.4mm)	Similar
Working Length(mm)	CHV-110J-U(Working Length:2000mm) CHV-US120J-U (Working Length:2150mm)	CHV-US100J-U (Working Length:2000mm) CHV-US110J-U (Working Length:2000mm)	Similar
Bending Angle(°)	CHV-110J-U (UP/DOWN:120°/120°, LEFT/RIGHT: 120°/120°) CHV-US120J-U (UP/DOWN:120°/120°, LEFT/RIGHT: 120°/120°)	CHV-US100J-U (UP/DOWN:120°/120°, LEFT/RIGHT: N/A) CHV-US110J-U (UP/DOWN:120°/120°, LEFT/RIGHT:120°/120°)	Same
Field of View	110°	110°	Same
Sterilization Method	EO SAL:10^{-6}	EO SAL:10^{-6}	Same

Suction Channel	Connect the suction pump to the suction port and turn on the suction pump to generate suction.	Connect the suction pump to the suction port and turn on the suction pump to generate suction.	Same
Water Jet Channel	Connect the irrigation pump to the water injection, and inject the irrigation solution through the irrigation channel.	Connect the irrigation pump to the water injection, and inject the irrigation solution through the irrigation channel.	Same

5.7 Substantial Equivalence

Flexible Video-Choledochoscope System, K222261 are used as predicate device compared to proposed device Flexible Video-Choledochoscope manufactured by Shanghai SeeGen Photoelectric Technology Co., Ltd.

5.8 Non-clinical Performance Data

The following performance tests were conducted to support substantial equivalence: mechanical performance; duodenoscope compatibility testing and flexible surgical instrument compatibility testing and comparison performance testing.

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, Section 5 510(k) Summary based on the information provided in this premarket notification, Shanghai SeeGen Photoelectric Technology Co., Ltd has demonstrated that proposed device Flexible Video-Choledochoscope is substantially equivalent to Shanghai SeeGen Photoelectric Technology Co., Ltd's currently marketed Flexible Video-Choledochoscope System, K222261.