April 20, 2023

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

Re: K222261
Trade/Device Name: Flexible Video-Choledochoscope System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBN, KQM, NTN, FET
Dated: March 17, 2023
Received: March 21, 2023

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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222261

Device Name
Flexible Video-Choledochoscope System

Indications for Use *(Describe)*
The Flexible Video-Choledochoscope System 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 System comprises two components: the Flexible Video- Choledochoscope and Imaging Processor System (Including Light Source).

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 imaging processor system (including the light source) provides illumination for Flexible Video-Choledochoscope and is also used to receive the signal from the endoscope, then convert it into an image and display it on the examination 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.

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:	April 4, 2023

5.2 Device

Device Name:	Flexible Video-Choledochoscope System
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

5.3 Predicate Device

Device Name:	SpyGlass DS and DS II Direct Visualization System, K183636
Common Name:	Choledochoscope and Accessories, Flexible/Rigid; Camera, Surgical and Accessories; LED light Source
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1 00
Regulation Name：	Endoscope and Accessories
Product Code:	FBN, KQM, NTN

5.4 Device Description

Flexible Video-Choledochoscope System is composed of sterile Flexible Video-Choledochoscope and a non-sterile Imaging Processor System (Including Light Source). The Flexible Video-Choledochoscope is composed of Operation section, Light-guide Section, Insertion section a Distal tip and bending section. The Operation Section is pulled by the wire rope to control the bending direction of the Distal tip.

The Light-guide section transmits the illumination light from the image processor to the Distal tip. The Insertion Tube is used to guide it into other instruments or cavity of the body. The Distal tip contains a camera system and a lighting system for illumination and observation.

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-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.

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 System 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 System comprises two components: the Flexible Video- Choledochoscope and Imaging Processor System (Including Light Source).

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 imaging processor system (including the light source) provides illumination for Flexible Video-Choledochoscope, and is also used to receive the signal from the endoscope, then convert it into an image and display it on the examination monitor.

5.6 Substantial Equivalence and Technological Characteristics

Item	Flexible Video-Choledochoscope System (**Proposed Device**)	SpyGlass DS and DS II Direct Visualization System, K183636	Comment
Indication for Use	The Flexible Video-Choledochoscope System 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 System comprises two components: the Flexible Video- Choledochoscope and Imaging Processor System (Including Light Source). 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 imaging processor system (including the light source) provides illumination for Flexible Video-Choledochoscope, and is also used to receive the signal from the endoscope, then convert it into an image and display	The SpyGlass DS and DS II Direct Visualization System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts. The SpyGlass DS and DS II Direct Visualization System comprises two components: the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter, and the SpyGlass DS Digital Controller. The SpyScope DS Access and Delivery Catheter and SpyScope DS II Access and Deliver Catheter are intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts. The SpyGlass DS Digital Controller is intended to	Almost the same.

	it on the examination monitor.	provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.	
Imaging Technology	CMOS chips at distal end	CMOS chips at distal end	Same.
Illumination Source	LED	LED	Same.
Distal End(mm) Outer Diameter	CHV-US100J-U (OD:3.3mm) CHV-US110J-U (OD:3.4mm）	3.5	Similar
Working Length (mm)	CHV-US100J-U (Working Length:2000mm) CHV-US110J-U (Working Length: 2000mm)	2140	Similar
bending angle (°)	CHV-US100J-U (UP/DOWN:120°/120°, LEFT/RIGHT: N/A) CHV-US110J-U (UP/DOWN:120°/120°, LEFT/RIGHT: 120°/120°)	SpyGlass DS AND SpyGlass DS II (UP/DOWN:90°/90°, LEFT/RIGHT: 90°/90°)	Similar
Field of View	110°±10°	120°	Almost the same.
Sterilization Method	ETO Sterilization	ETO Sterilization	Same.
Suction Channel	Connect the suction pump to the suction port and turn on the suction. pump to generate suction.	Suction holes are used for extracting liquid through intervention channels.	Same.
Water Jet Channel	Connect the irrigation pump to the water injection, and inject the irrigation solution through the irrigation channel.	Irrigation holes are used to inject irrigation solution through two dedicated irrigation channels to release vision and stretch the pipeline.	Almost the same.

Item	Flexible Video-Choledochoscope System (Proposed Device) The following type: PL-1000	SpyGlass DS Digital Controller, K183636(Primary Predicate Device)	Comment
Indication for Use	The imaging processor system (including the light source) provides illumination for Flexible Video-Choledochoscope, and is also used to receive the signal from the endoscope, then convert it into an image and display it on the examination monitor.	The SpyGlass DS Digital Controller is intended to provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.and Delivery Catheter and SpyScope DS II Access and Delivery Catheter are intended to provide direct visualization and to guide both optical and accessory	Almost the same.
input voltage	100 – 240V	100 – 240V	Same
frequency	50/60 Hz	50/60 Hz	Same
Operating temperature	5-40°C	10-35°C	Similar
Storage temperature	-20-50°C	-40-70°C	Similar
Type of protection against electric shock	Class I	Class I	Same
Protection class of applicati	BF	BF	Same

on parts			
light source	Have	Have	Same
Light control	Have	Have	Same
Light source brightness indication	Have	Have	Same
image processing	Have	Have	Same
DVI	Have	Have	Same
VGA	/	VGA (1280×1024)	
S-Video	S-Video	S-Video	Same
CVBS	CVBS (720*576)	/	
USB	Have	Have	Same
Potential equalization terminal	Have	Have	Same
Heat dissipation design	Cooling fan	Cooling fan	Same
electromagnetic radiation	Group 1 Class A	Group 1 Class A	Same
electromagnetic immunity	Compliance with EMC standards	Compliance with EMC standards	Same

5.7 Substantial Equivalence

SpyGlass DS and DS II Direct Visualization System, K183636 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-Choledochoscope System has been successfully tested for its functions and performance per ISO 8600-1/3/4 and mechanical characteristics. 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.

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-Choledochoscope System is substantially equivalent to Boston Scientific Corporation's currently marketed SpyGlass DS and DS II Direct Visualization System, K183636.