February 22, 2022

Shanghai SeeGen Photoelectric Technology Co., Ltd
% Nick Wang
RA Specialist
Shanghai Vanhe Consulting Co., Ltd
2F, Building No.1, 3938 Huqingping Road
Shanghai, Shanghai 201713
China

Re: K211686
Trade/Device Name: Flexible Video-Choledo-Cysto-Ureteroscope System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FGB, FBN, FET, FAJ, FGA
Dated: January 17, 2022
Received: January 21, 2022

Dear Nick Wang:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211686

Device Name
Flexible Video-Choledo-Cysto-Ureteroscope System

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.

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Section 5
510(k) Summary

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:	Nick Wang RA Specialist Shanghai Vanhe Consulting Co., Ltd Address: 2F, Building No.1, 3938 Huqingping Road, Qingpu District, Shanghai, China. Phone: 0086-13585860297 Email: vanheconsulting@126.com
Date Prepared:	May 27, 2021

5.2 Device

Device Name:	Flexible Video-Choledo-Cysto-Ureteroscope System
Common Name:	Ureteroscope And Accessories, Flexible/Rigid; Choledochoscope And Accessories, Flexible/Rigid; Endoscopic Video Imaging System/Component, Gastroenterology-Urology; Cystoscope and Accessories, Flexible/Rigid; Kit, Nephroscope
Regulatory Class:	II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	FGB, FBN, FET, FAJ, FGA

5.3 Predicate Device

Device Name:	Flexible Video-Uretero-Choledochoscope System, K142556
Common Name:	Ureteroscope And Accessories, Flexible/Rigid; Choledochoscope And Accessories, Flexible/Rigid;
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	FGB, FBN

5.4 Device Description

Flexible Video-Choledo-Cysto-Ureteroscope System is composed of sterile Flexible Video-Choledo-Cysto-Ureteroscope and an non-sterile Imaging Processor System (Including Light Source).The Flexible Video-Choledo-Cysto-Ureteroscope is composed of Control Section, Light-guiding Section, Connector Section, Insertion Tube and Distal End. The Control Section is pulled by the wire rope to control the bending direction of the Distal End.

The Light-guide section transmits the illumination light from the image processor to the Distal End. The Insertion Tube is used to guide it into other instruments or cavity of the body. The Distal End 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-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	Flexible Video-Choledo-Cysto-Ureteroscope System(**Proposed Device**)	Flexible Video-Uretero-Choledochoscope System, K142556
Indication for Use	The Flexible Video-Choledo-Cysto-Ureteroscope System is indicated for	The KARL STORZ Flexible Video-Uretero-

Item	Flexible Video-Choledo-Cysto-Ureteroscope System(**Proposed Device**)	Flexible Video-Uretero-Choledochoscope System, K142556
	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.	Choledochoscope 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-Uretero-Choledochoscope System is also indicated for the examination of bile ducts, and using additional accessories, to perform various diagnostic and therapeutic procedures during cholecystectomy
Imaging Technology	CMOS chips at distal end	CMOS chips at distal end
Illumination Source	LED	LED
Distal End(mm) Outer Diameter	UV-US110-H (OD:2.5mm） UV-US100-H (OD:3.0mm） UV-100-E (OD:4.7mm） UV-100T-E (OD:5.3mm） UV-110-E (OD:4.7mm） UV-110T-E (OD:5.3mm） CHV-US100-H (OD:3.0mm) CHV-100-E(OD:4.7mm) CHV-100T-E(OD:5.3mm)	2.9
Working Length(mm)	380, 600, 750	700
Deflection(°) of view	UV-US110-H (UP/DOWN:275°/275°） UV-US100-H (UP/DOWN:275°/275°） UV-100-E (UP/DOWN:210°/130°）	Up:270 Down:270

Item	Flexible Video-Choledo-Cysto-Ureteroscope System(**Proposed Device**)	Flexible Video-Uretero-Choledochoscope System, K142556
	UV-100T-E (UP/DOWN:210°/130°） UV-110-E (UP/DOWN:210°/130°） UV-110T-E (UP/DOWN:210°/130°） CHV-US100-H(UP/DOWN:120°/120°) CHV-100-E(UP/DOWN:160°/130°) CHV-100T-E(UP/DOWN:160°/130°)	
Field of View	110°	90°
Sterilization Method	ETO Sterilization	Reusable

Device Name	Imaging Processor System (Including Light Source)	Image1 HD HUB CCU(Predicate Device)K142556
Brightness Control	Yes	Yes
Enhancement Control(Contrast and Definition)	Yes	Yes
Shutter Speed	1/1141-1/13860 sec	1/60-1/17000 sec
White Balance	Yes	Yes
Zoom	Yes	Yes
Output Formats	NTSC/PAL/DVI	NTSC/PAL/VGA/DVI/SDI
Image/Video Capture	Yes	Yes
Video Format Inputs(Cameras)	SD and HD	SD and HD
Video Format Outputs	SD and HD	SD and HD

5.7 Substantial Equivalence

Flexible Video-Uretero-Choledochoscope System, K142556 is used as predicate device compared to proposed device Flexible Video-Choledo-Cysto-Ureteroscope 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 and performance per ISO 8600-1/3/4 and mechanical characteristics. Safety testing war 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 and EO residual.

5.8 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 Flexible Video-Uretero-Choledochoscope System, K142556.