



November 22, 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: K222499
Trade/Device Name: Disposable Endoscope Valves Kit
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: November 3, 2023
Received: November 3, 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 (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.

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

Indications for Use

510(k) Number (if known)
K222499

Device Name
Disposable Endoscope Valves Kit

Indications for Use (Describe)

The valves are used in conjunction with conventional gastrointestinal endoscope to control the functions of water/gas injection and suction during the endoscopic operation.

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.

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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:	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:	July 15, 2022

5.2 Device

Device Name:	Disposable Endoscope Valves Kit
Common Name:	Endoscope Channel Accessory
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and Accessories
Product Code:	ODC

5.3 Predicate Device

Device Name:	Disposable Endoscopy Adapter Set, K220210
Common Name:	Endoscope Channel Accessory
Regulatory Class:	Class II
Regulation Number:	21 CFR 876.1500
Regulation Name:	Endoscope and Accessories
Product Code:	ODC

5.4 Device Description

Disposable Endoscope Valves Kit consists of Water/gas button, Attraction button, Biopsy cap and Water injection adapter. Disposable Endoscope Valves Kit connect the endoscope operating handle matched with the model, and install the water gas button into the water gas port of the operating handle; Align the positioning boss of the suction button with the card slot of the operating handle and install it into the suction port; Install the biopsy cap into the clamp opening of the operating handle.

5.5 Indication for Use:

The valves are used in conjunction with conventional gastrointestinal endoscope to control the functions of water/gas injection and suction during the endoscopic operation.

5.6 Substantial Equivalence and Technological Characteristics

Item	Disposable Endoscope Valves Kit (Proposed Device)	Disposable Endoscopy Adapter Set, K220210	Discussion
Indication for Use	The valves are used in conjunction with conventional gastrointestinal endoscope to control the functions of water/gas injection and suction during the endoscopic operation.	<p>The Disposable Endoscopy Adapter Set is a collection of several sterile units. It is intended to be fitted to multiple endoscope working channels/ports to control the flow of fluids, gases and other materials.</p> <ul style="list-style-type: none"> - Disposable Air/Water Valve: This unit is intended to be fitted to an endoscope air/water channel to control the inflow of medical gases and water, whilst preventing back-flow. - Disposable Suction Valve: This unit is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air. - Disposable Biopsy Valve: This unit is intended to be fitted to an endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure. - Disposable Water Jet Adapter: This unit is intended 	Substantially equivalent

Item	Disposable Endoscope Valves Kit (Proposed Device)	Disposable Endoscopy Adapter Set, K220210	Discussion
		to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	
Product Code	ODC	ODC	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Classification	II	II	Same
Water/gas button		Air/Water Valve	
Compatible Endoscopes	OLYMPUS 100/200 series upper and lower gastrointestinal electronic endoscopes FUJIFILM 600/700 series upper and lower gastrointestinal electronic endoscopes PENTAX i10/90K series upper and lower gastrointestinal electronic endoscopes PENTAX NP1 series upper and lower gastrointestinal electronic endoscopes PENTAX NP2 series upper and lower gastrointestinal electronic endoscopes	Olympus 140/160/180/190/240/260/290 series endoscopes; PENTAX GI Video Endoscope 90K/90i Series, K10/i10 Series; Fujifilm® 500/600/ 700 series endoscopes	Substantially equivalent supported by bench testing.
Sterile	EO Sterilization	EO Sterilization	Same
Material	Polycarbonate, Silicone rubber, Stainless Steel	Silicone Rubber, ABS, SUS304	Substantially equivalent supported by biocompatibility testing.
Environment Use	Hospital/clinics	Hospital/clinics	Same
Suction button		Suction Valve	
Compatible Endoscopes	OLYMPUS 100/200 series upper and lower gastrointestinal electronic endoscopes FUJIFILM 600/700 series upper and lower	Olympus 140/160/180/190/240/260/290 series endoscopes; PENTAX GI Video Endoscope 90K/90i Series, K10/i10 Series;	Substantially equivalent supported by bench testing.

Item	Disposable Endoscope Valves Kit (Proposed Device)	Disposable Endoscopy Adapter Set, K220210	Discussion
	gastrointestinal electronic endoscopes PENTAX i10/90K series upper and lower gastrointestinal electronic endoscopes PENTAX NP1 series upper and lower gastrointestinal electronic endoscopes PENTAX NP2 series upper and lower gastrointestinal electronic endoscopes	Fujifilm® 500/600/ 700 series endoscopes	
Sterile	EO Sterilization	EO Sterilization	Same
Material	Polycarbonate, Silicone rubber, Stainless Steel	ABS, Silicone, Rubber, SUS304	Substantially equivalent supported by biocompatibility testing.
Environment Use	Hospital/clinics	Hospital/clinics	Same
Biopsy cap		Biopsy Valve	
Compatible Endoscopes	OLYMPUS 100/200 series upper and lower gastrointestinal electronic endoscopes FUJIFILM 600/700 series upper and lower gastrointestinal electronic endoscopes PENTAX i10/90K series upper and lower gastrointestinal electronic endoscopes PENTAX NP1 series upper and lower gastrointestinal electronic endoscopes PENTAX NP2 series upper and lower gastrointestinal electronic endoscopes	Olympus 140/160/180/190/240/260/290 series endoscopes; PENTAX GI Video Endoscope 90K/90i Series, K10/i10 Series; Fujifilm® 500/600/ 700 series endoscopes	Substantially equivalent supported by bench testing.
Sterile	EO Sterilization	EO Sterilization	Same
Material	Silicone Rubber	Silicone Rubber	Same

Item	Disposable Endoscope Valves Kit (Proposed Device)	Disposable Endoscopy Adapter Set, K220210	Discussion
Environment Use	Hospital/clinics	Hospital/clinics	Same
Water injection adapter		Water Jet Adapter	
Compatible Endoscopes	OLYMPUS 100/200 series upper and lower gastrointestinal electronic endoscopes FUJIFILM 600/700 series upper and lower gastrointestinal electronic endoscopes PENTAX i10/90K series upper and lower gastrointestinal electronic endoscopes PENTAX NP1 series upper and lower gastrointestinal electronic endoscopes PENTAX NP2 series upper and lower gastrointestinal electronic endoscopes	Olympus 140/160/180/190/240/260/290 series endoscopes; PENTAX GI Video Endoscope 90K/90i Series, K10/i10 Series; Fujifilm® 500/600/ 700 series endoscopes	Substantially equivalent supported by bench testing.
Sterile	EO Sterilization	EO Sterilization	Same
Material	Polycarbonate, Silicone rubber	Metal Type: PC, SUS303, Silicone Rubber, Plastic Type: PC, Silicone Rubber	Same as Plastic Type
Environment Use	Hospital/clinics	Hospital/clinics	Same

5.7 Substantial Equivalence

Disposable Endoscopy Adapter Set, K220210 are used as predicate device compared to proposed device Disposable Endoscope Valves Kit manufactured by Shanghai SeeGen Photoelectric Technology Co., Ltd.

5.8 Non-clinical Performance Data

The proposed device meets the requirements of ISO 10993 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing”, ISO 11135-1 “Sterilization of Health Care products Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”, and ISO 10993-7 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals”.

The following bench tests were performed on Disposable Endoscopy Adapter Set: Appearance, Physical properties. The results of all testing were passing.

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 Disposable Endoscope Valves Kit is substantially equivalent to Yangzhou Fartley Medical Instrument Technology Co., Ltd.'s currently marketed Disposable Endoscopy Adapter Set, K220210.