November 21, 2022

Yangzhou Fartley Medical Instrument Technology Co., Ltd.
Tina Han, RA Specialist
Beizhou Road, Lidian Town, Guangling District
Yangzhou, Jiangsu 225106
CHINA

Re: K222980
Trade/Device Name: Pentax Medical Valve Set
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: September 16, 2022
Received: September 28, 2022

Dear Tina Han:

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)*
K222980

Device Name
Pentax Medical Valve Set

Indications for Use *(Describe)*
The Pentax Medical Valve Set is a collection of several sterile units. It is intended to be fitted to Pentax endoscopes' working channels/ports to control the flow of fluids, gases and other materials.

- 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 to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

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:	Yangzhou Fartley Medical Instrument Technology Co., Ltd. Address:Beizhou Road, Lidian Town, Guangling District, Yangzhou 225106 Jiangsu, China
Contact Person:	Han Xi RA Specialist Phone: 0086-15051101225 Email: th@fartley.com
Date Prepared:	September 20, 2022

5.2 Device

Device Name:	Pentax Medical Valve Set
Classification Name:	Endoscope Channel Accessory
Regulatory 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
Manufacturer:	Yangzhou Fartley Medical Instrument Technology Co., Ltd.
Classification Name:	Endoscope Channel Accessory
Regulatory Class:	II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	ODC

5.4 Device Description

The Pentax Medical Valve Set is a collection of several sterile units. It is intended to be fitted to Pentax endoscopes' working channels/ports to control the flow of fluids, gases and other materials. The sterile units may consist of Disposable Air/Water Valve, Disposable Suction Valve, Disposable Biopsy Valve and Disposable Water Jet Adapter. Disposable Endoscopy Adapter Set may be configured as single valve or multiple valves in any combination up to a maximum of 4 valves.

5.5 Indication for Use:

The Pentax Medical Valve Set is a collection of several sterile units. It is intended to be fitted to

Pentax endoscopes' working channels/ports to control the flow of fluids, gases and other materials.

- 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 to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

5.6 Comparison of Technological Characteristics

The Pentax Medical Valve Set consist of Disposable Air/Water Valve, Disposable Suction Valve, Disposable Biopsy Valve and Disposable Water Jet Adapter which are compatible with Pentax endoscopes,our existing predicated device of Disposable Endoscopy Adapter Set,K220210 also consist of Pentax series of Disposable Air/Water Valve, Disposable Suction Valve, Disposable Biopsy Valve and Disposable Water Jet Adapter.

The Disposable Air/Water Valve, Disposable Suction Valve and Disposable Water Jet Adapter among them are completely same,the only difference is the valve cap of Disposable Biopsy Valve.

Thus,the Pentax Medical Valve Set has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in our existing predicated device of Disposable Endoscopy Adapter Set,K220210. The differences between the proposed device and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below.

Item	Pentax Medical Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set,K220210	Discussion
Indication for Use	The Pentax Medical Valve Set is a collection of several sterile units. It is intended to be fitted to Pentax endoscopes' working channels/ports to control the flow of fluids, gases and other materials. - Disposable Air/Water Valve: This unit is	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. - 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.	Substantially equivalent

Item	Pentax Medical Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set,K220210	Discussion
	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 to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	- 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 to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	
Product	ODC	ODC	Same

Item	Pentax Medical Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set,K220210	Discussion
Code			
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Classification	II	II	Same
Air/Water Valve			
Compatible Endoscopes	PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series	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, ABS, SUS304	Silicone Rubber, ABS, SUS304	Substantially equivalent supported by biocompatibility testing.
Environment Use	Hospital/clinics	Hospital/clinics	Same
Suction Valve			
Compatible Endoscopes	PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series	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	ABS, Silicone Rubber, SUS304	ABS, Silicone Rubber, SUS304	Substantially equivalent supported by biocompatibility testing.
Environment Use	Hospital/clinics	Hospital/clinics	Same
Biopsy Valve			
Compatible Endoscopes	PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series;	Olympus 140/160/180/190/240/260/290 series endoscopes; PENTAX GI Video	Substantially equivalent supported by bench testing.

Item	Pentax Medical Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set,K220210	Discussion
		Endoscope 90K/90i Series; K10/i10 Series; Fujifilm® 500/600/ 700 series endoscopes	
Sterile	EO Sterilization	EO Sterilization	Same
Material	Silicone Rubber	Silicone Rubber	Same
Environment Use	Hospital/clinics	Hospital/clinics	Same
Water Jet Adapter			
Compatible Endoscopes	PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series;	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	Metal Type:PC, SUS303,Silicone Rubber Plastic Type: PC, Silicone Rubber	Metal Type:PC, SUS303,Silicone Rubber Plastic Type: PC, Silicone Rubber	Substantially equivalent supported by biocompatibility testing.
Environment Use	Hospitals/clinics	Hospitals/clinics	Same

5.7 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 Pentax Medical Valve Set: Appearance, Physical properties. The results of all testing were passing.

5.8 Clinical Test Data

No Clinical Study is included in this submission.

5.9 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Yangzhou Fartley Medical Instrument Technology Co., Ltd. has demonstrated that proposed device Pentax Medical Valve Set is substantially equivalent to our existing predicated device of Disposable Endoscopy Adapter Set,K220210.