June 20, 2025

Yangzhou Fartley Medical Instrument Technology Co,. Ltd
Xi Han
Regulatory Affairs Manager
Beizhou Road
Yangzhou, Jiangsu 225106
China

Re: K250732
Trade/Device Name: Disposable Endoscopy Valve Set
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: March 11, 2025
Received: March 11, 2025

Dear Xi 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 (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,

SIVAKAMI VENKATACHALAM -S

for
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.

510(k) Number *(if known)*
K250732

Device Name
Disposable Endoscopy Valve Set

Indications for Use *(Describe)*
The Disposable Endoscopy Valve 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.

- 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 designed to prevent backflow and 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.

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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.

1.1 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:	May 13, 2025

1.2 Device

Device Name:	Disposable Endoscopy Valve Set
Classification Name:	Endoscope Channel Accessory
Regulatory Class:	II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	ODC

1.3 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

1.4 Device Description

The Disposable Endoscopy Valve Set is a collection of several sterile units. It is intended to be fitted to different 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.

1.5 Indication for Use:

The Disposable Endoscopy Valve 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.
- 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.

1.6 Comparison of Technological Characteristics

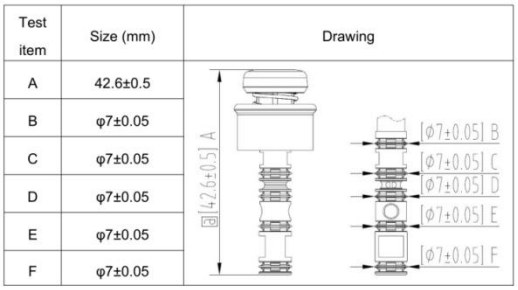
The Disposable Endoscopy Valve Set consist of Disposable Air/Water Valve, Disposable Suction Valve, Disposable Biopsy Valve and Disposable Water Jet Adapter, our existing predicated device of Disposable Endoscopy Adapter Set,K220210 also consist of Pentax series of Disposable Air/Water Valve, Disposable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

The Disposable Endoscopy 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.

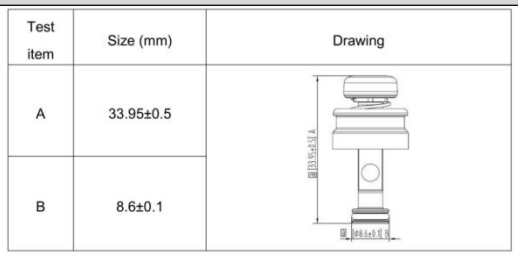
Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
Indication for Use	The Disposable Endoscopy Valve Set is a collection of several sterile units. It is intended to be fitted to multiple endoscope working channels/ports to control the flow of 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. - 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	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. - Disposable Suction Valve: This unit is intended to be fitted to an endoscope	Substantially equivalent

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
	intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	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 Code	ODC	ODC	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Classification	II	II	Same
Air/Water Valve			
Compatible Endoscopes	PENTAX GI Video Endoscope i20 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.
Performance Characteristics	- Appearance a. The surface of Plastic part should be smooth, clean and uniform in colour, and there should be no defects such as flashes, scratches, microcosm, plastic flow, oil stains, defects, breakages and so on; b. The surface of Rubber part should be smooth, clean, uniform in colour, with no rubber threads, rubber chippings, foreign matters, dirt, deformations, fractures,	- Appearance a. The surface of Plastic part should be smooth, clean and uniform in colour, and there should be no defects such as flashes, scratches, microcosm, plastic flow, oil stains, defects, breakages and so on;	Substantially equivalent supported by bench testing.

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
	defects, blooming, singe and so on; c. Spring surface should be smooth and clean, without flashes, oil stains, scratches, deformations and so on; d. The assembly direction and position of each part should be correct and the assembly should be in place. - Connection firmness Pentax I20 Air/Water Valve shall be able to withstand axial static tension of 15N for 15s without falling off. - Fitting performance Pentax I20 Air/Water Valve should be switched smoothly without obstruction. After pressing down on the lid, it can quickly and smoothly return to its original position within 1s. - Corrosion resistance The Spring should have good corrosion resistance, if there is a corrosion trace, it can be removed after wiping. - Depression force The initial pressure of the Pentax I20 Air/Water Valve should be between 6.5 and 9.0N, and the complete pressure should be no more than 13.0N. - Air feeding performance The air feeding volume of Pentax I20 Air/Water Valve should be greater than or equal to 950ml per minute. There shall be no water feeding during air feeding, and should be no water leakage at the connection between the Air/Water Valve and the endoscopic Air/Water Valve hole seat. - Water feeding performance The water feeding volume of Pentax I20 Air/Water Valve should be greater than or equal to 45ml per minute. There shall be no air feeding during water feeding, and should be no air leakage at the connection between the Air/Water Valve and the endoscopic	b. The surface of Rubber part should be smooth, clean, uniform in colour, with no rubber threads, rubber chippings, foreign matters, dirt, deformations, fractures, defects, blooming, singe and so on; c. Spring surface should be smooth and clean, without flashes, oil stains, scratches, deformations and so on; d. The assembly direction and position of each part should be correct and the assembly should be in place. - Connection firmness Air/Water Valve shall be able to withstand axial static tension of 15N for 15s without falling off. - Fitting performance a. Air/Water Valve should be switched smoothly and with no obstruction. b. When Air/Water Valve is used in combination with the corresponding endoscope, they can cooperate well and be able to perform corresponding functions. - Depression force Air/Water Valve shall be pressed down for a distance of 3mm, and the depression force shall not exceed 12N. - Air feeding performance	

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
	Air/Water Valve hole seat. - Sealing performance a. Without plugging or pressing the Pentax I20 Air/Water Valve, the front end of the endoscope should have no air or liquid leakage at a maximum depth of 30mm in the water. b. Without plugging or pressing the Pentax I20 Air/Water Valve, the counterflow rate should be less than 0.1ml/min. - Size  	The time required to feed air into the closed container to make its pressure reach 8KPa shall not exceed 12s. - Water feeding performance Feed water into the measuring cylinder to 10ml, and the time required shall not exceed 12s. - Sealing performance a. The hole of Air/Water Valve shall be free of water leakage. There shall be no liquid and air leakage at the connection between Air/Water Valve and the endoscopic Air/Water Valve hole seat. b. Without plugging or pressing the Air/Water Valve, there should be no air and liquid leakage at the front end of the endoscope.	
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 i20 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.

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
Performance Characteristics	- Appearance a. The surface of Plastic part should be smooth, clean and uniform in colour, and there should be no defects such as flashes, scratches, microcosm, plastic flow, oil stains, defects, breakages and so on; b. The surface of Rubber part should be smooth, clean, uniform in colour, with no rubber threads, rubber chippings, foreign matters, dirt, deformations, fractures, defects, blooming, singe and so on; c. Spring surface should be smooth and clean, without flashes, oil stains, scratches, deformations and so on; d. The assembly direction and position of each part should be correct and the assembly should be in place. - Connection firmness a. Pentax I20 Suction Valve shall be able to withstand axial static tension of 15N for 15s without falling off. - Fitting performance a. Pentax I20 Suction Valve should be switched smoothly without obstruction. After pressing down on the lid, it can quickly and smoothly return to its original position within 1s. - Depression force **a.** The initial pressure of the Pentax I20 Suction Valve should be between 1.3 and 5.0N, and the complete pressure should be no more than 12.0N. - Suction performance a. The water suction volume of Pentax I20 Suction Valve shall be no less than 850ml per minute. - Anti-self-suction performance When the Pentax I20 Suction Valve are not pressed (working), there shall be no self-suction. - Sealing performance of water feeding When feeding water from the Biopsy Valve inlet, the Pentax I20 Suction Valve shall be free of falling off or water leakage. -Size	- Appearance a. The surface of Plastic part should be smooth, clean and uniform in colour, and there should be no defects such as flashes, scratches, microcosm, plastic flow, oil stains, defects, breakages and so on; b. The surface of Rubber part should be smooth, clean, uniform in colour, with no rubber threads, rubber chippings, foreign matters, dirt, deformations, fractures, defects, blooming, singe and so on; c. Spring surface should be smooth and clean, without flashes, oil stains, scratches, deformations and so on; d. The assembly direction and position of each part should be correct and the assembly should be in place. - Connection firmness Suction Valve shall be able to withstand axial static tension of 15N for 15s without falling off. - Fitting performance a. Suction Valve should be switched smoothly and with no obstruction. b. When Suction Valve is used in combination with the corresponding endoscope, they can cooperate well and be	Substantially equivalent supported by bench testing.

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
		able to perform corresponding functions. - Depression force Suction Valve shall be pressed down for a distance of 3mm, and the depression force shall not exceed 12N. - Suction performance The suction time of 200mL water shall not exceed 20 seconds. - Anti-self-suction performance When the Suction Valve is not pressed (working), there shall be no self-suction.	
Sterile	EO Sterilization	EO Sterilization	Same
Material	ABS, Silicone Rubber, SUS304, PC	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 PENTAX GI Video Endoscope i20 Series; Note: Different model matches the different endoscopes, more details, please refer to Section Device Description.	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.
Performance Characteristics	- Appearance a. The surface of Biopsy Valve should be smooth, clean ,uniform in colour, with no rubber threads, rubber chippings, foreign matters, dirt, deformations, fractures,	- Appearance a. The surface of Biopsy Valve should be smooth, clean ,uniform in	Substantially equivalent supported by bench testing.

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
	defects, blooming, singe and so on. b. Cutting position is correct and fully opened up. c. If Biopsy valve is with irrigation port, the surface of Plastic part should be smooth, clean and uniform in colour, and there should be no defects such as flashes, scratches, microcosm, plastic flow, oil stains, defects, breakages and so on. - Fitting performance When Biopsy Valve is used in combination with the corresponding endoscope and endoscopic instruments, it shall not fall off, and the closure shall not be opened. The Biopsy Valve should not be damaged. - Sealing performance When Biopsy Valve is used in combination with the corresponding endoscope and endoscopic instruments, there shall be no liquid leakage at each joint. When Pentax Biopsy valve is for simulated use, the lid should not be opened. There shall be no leakage at the cutting position of the lid and the lid must not shift. - Use performance The opening and closing of the lid shall be smooth, and the Biopsy Valve shall have no damage. - Connection firmness If Biopsy valve is with irrigation port, the connection between Check valve and Biopsy valve should be able to withstand axial static tensile force of 15N for 15s without falling off. - Liquid leakage Apply the pressure on the conical locking connector between 300kpa and 330kpa for 30s to 35s, and the inner conical locking connector	colour, with no rubber threads, rubber chippings, foreign matters, dirt, deformations, fractures, defects, blooming, singe and so on. b. Cutting position is correct and fully opened up. - Fitting performance When Biopsy Valve is used in combination with the corresponding endoscope and endoscopic instruments, it shall not fall off, and the closure shall not be opened. - Sealing performance In simulation use, when Suction Valve works, there shall be no liquid leakage at the joint between the instrument and the pressure cap of Biopsy Valve (when there is no instrument penetration, observe the opening of the pressure cap of Biopsy Valve) and the joint between Biopsy valve and Biopsy Valve seat.	

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
	shall have no leakage. - Air leakage Apply the pressure on the conical locking connector between -80kpa and -88kpa for 15s to 20s, and the leakage shall not exceed 0.005 pa * m 3. - Stress cracking Conical locking connector shall be free of cracking. - Axial separation force After bearing the axial tension of 35N for 10s, the inner conical locking connector of Biopsy Valve shall not separate from the connection of reference connector. - Resistance to overriding When bearing the torque of 0,15 N·m to 0,17 N·m for 5-10 seconds, the inner conical locking connector of Biopsy Valve shall not exceed the thread or lug of the reference connector. - Unscrewing torque When unscrewing torque is between 0,018 N·m to 0,020 N·m. for 10-15 seconds, the inner conical locking connector of Biopsy Valve shall not separate from the connection of reference connector. - Pressure resistance in counterflow direction The counterflow direction of Biopsy Valve shall be able to withstand the pressure of 200KPa. - Blocking performance Biopsy Valve should be closed under pressure of no more than 2kPa in counterflow direction.		

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
	- Opening pressure Biopsy Valve shall be opened at the pressure not greater than 2kPa.		
Sterile	EO Sterilization	EO Sterilization	Same
Material	Silicone Rubber, PC	Silicone Rubber	Substantially equivalent supported by biocompatibility testing.
Environment Use	Hospital/clinics	Hospital/clinics	Same
Disposable Water Jet Adapter			
Compatible Endoscopes	PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series; PENTAX GI Video Endoscope i20 Series; Note: Different model matches the different endoscopes, more details, please refer to Section Device Description.	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.
Performance Characteristics	- Appearance The surface of Plastic part shall be smooth, clean and uniform in colour, and there should be no defects such as flashes, scratches, microcosm, plastic flow, oil stains, defects, breakages and so on. - Connection firmness Disposable Water Jet Connector shall be able to withstand axial static tension of 15N for 15s without falling off. - Leakage Install Disposable Water Jet Adapter on the corresponding endoscope, and each connection of Disposable Water Jet Adapter should have no water leakage. - Liquid leakage Apply the pressure on the conical locking connector between 300kpa and 330kpa for 30s	- Appearance The surface of Plastic part shall be smooth, clean and uniform in colour, and there should be no defects such as flashes, scratches, microcosm, plastic flow, oil stains, defects, breakages and so on; the surface of Metal part should be smooth and clean, without burrs, oil stains, sharp edge blunt and so on. - Connection firmness Disposable Water Jet Connector shall be able to withstand axial static tension of 15N for 15s without falling off.	Substantially equivalent supported by bench testing.

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
	to 35s, and the inner conical locking connector shall have no leakage. - Air leakage Apply the pressure on the conical locking connector between -80kpa and -88kpa for 15s to 20s, and the leakage shall not exceed 0.005 pa * m3. - Stress cracking Conical locking connector shall be free of cracking. - Axial separation force After bearing the axial tension of 35N for 10s, the inner conical locking connector of Disposable Water Jet Adapter shall not separate from the connection of reference connector. - Resistance to overriding When bearing the torque of 0,15 N·m to 0,17 N·m for 5-10 seconds, the inner conical locking connector of Disposable Water Jet Adapter shall not exceed the thread or lug of the reference connector. - Unscrewing torque When unscrewing torque is between 0,018 N·m to 0,020 N·m. for 10-15 seconds, the inner conical locking connector of Disposable Water Jet Adapter shall not separate from the connection of reference connector. - Pressure resistance in counterflow direction The counterflow direction of Disposable Water Jet Adapter shall be able to withstand the pressure of 200KPa. - Blocking performance Disposable Water Jet Adapter should be closed under pressure of no more than 2kPa in	- Fitting performance When Disposable Water Jet Connector is used in combination with the corresponding endoscope, they can cooperate well and be able to perform corresponding functions. - Leakage The connection of Disposable Water Jet Connector should have no leakage. - Pressure resistance in counterflow direction The counterflow direction of Disposable Water Jet Connector shall be able to withstand the pressure of 200KPa. - Opening pressure The Disposable Water Jet Connector shall be opened at the pressure not greater than 2kPa.	

Item	Disposable Endoscopy Valve Set(**Proposed Device**)	Disposable Endoscopy Adapter Set, K220210	Discussion
	counterflow direction. - Opening pressure The Disposable Water Jet Adapter shall be opened at the pressure not greater than 2kPa. - Fitting performance When Disposable Water Jet Connector is used in combination with the corresponding endoscope, they can cooperate well and be able to perform corresponding functions.		
Sterile	EO Sterilization	EO Sterilization	Same
Material	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

1.7 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 Disposable Endoscopy Valve Set: Appearance, Physical properties. The results of all testing were passing.

1.8 Clinical Test Data

No Clinical Study is included in this submission.

1.9 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 Disposable Endoscopy Valve Set is substantially equivalent to our existing predicated device of Disposable Endoscopy Adapter Set,K220210.