October 1, 2024

Alton (Shanghai) Medical Instruments Co. Ltd
Johnny Song
R&D Engineer
No.24 Building Jinshao Rd.1688, Baoshan District
Shanghai, Shanghai 200949
China

Re: K241285
Trade/Device Name: Disposable Endoscope Valves Set (AF series)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: May 7, 2024
Received: August 29, 2024

Dear Johnny Song:

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,

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

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)*
K241285

Device Name
Disposable Endoscope Valves Set (AF series)

Indications for Use *(Describe)*
The Disposable Endoscope Valve Sets 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. It includes an Air/Water Valve, a Suction Valve, a Biopsy Valve and an Auxiliary Water Connector.
- 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.
- 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.
- 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.
- Auxiliary Water Connector: 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.

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510(k) Summary

I. SUBMITTER

Name: Alton (Shanghai) Medical Instruments Co. Ltd.

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Date prepared: 2024-09-27

II. Identification of Subjective Device

Device trade name: Disposable Endoscope Valves Set (AF series)

Regulation Name: Endoscope and accessories

Regulation number: 21CFR 876.1500

Regulation class: 2

Review Panel: Gastroenterology/Urology

Product Code Description: Endoscope Channel Accessory

Product code: ODC

III. Identification of Predicate device

Predicate Submission Number: K220884

Trade/Device Name: Disposable Endoscope Valve Sets

Regulation Name: Endoscope and accessories

Regulation Number: 21 CFR 876.1500

Regulatory Class: 2

Review Panel: Gastroenterology/Urology

Product Code Description: Endoscope Channel Accessory

Product Code: ODC

IV. Device description

The Disposable Endoscope Valves Set is a collection of several sterile units, it is intended for single-use and supplied sterile. The subject device is intended to be fitted to multiple endoscope working channels/ports to control the flow of fluids, gases and other materials. It includes an Air/Water Valve, a Suction Valve, a Biopsy Valve and an Auxiliary Water Connector.

- The Suction Valve component of the Disposable Endoscope Valves Set is designed to be attached to the suction port of the endoscope, allowing the user to aspirate excess fluids or other debris obscuring the endoscopic image.
- The Air/Water Valve component of the Disposable Endoscope Valves Set is designed to be attached to the air/ water port of the endoscope, the activation of the air/ water valve allows the user to control air and water flow to assist in cleansing the lens during procedures.
- The Biopsy Valve component of the Disposable Endoscope Valves Set is intended to cover the endoscope biopsy port during an endoscopy procedure. In addition, the valve provides access for endoscopic device passage and exchange, helps maintain insufflation, and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.
- The Auxiliary Water Connector component of the Disposable Endoscope Valves Set is designed to be attached to the auxiliary water port of the endoscopes. The auxiliary water connector consists of a backflow valve that prevents the backflow of water or biomaterials from the endoscope to the sterile water bottle. And there were no prior submissions for the subject devices.

V. Indication for use

The Disposable Endoscope Valves 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. It includes an Air/Water Valve, a Suction Valve, a Biopsy Valve and an Auxiliary Water Connector.

- 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.

- 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.

- 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.

- Auxiliary Water Connector: This unit is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

VI. Comparison of technological characteristics with the predicate device

Attribute	Subject device	Predicative device (K220884)	Discussion/ Conclusion
Manufacturer	Alton (Shanghai) Medical Instruments Co. Ltd	SML Med-Tech Solutions Limited	/
Trade name	Disposable Endoscope Valves Set (AF series)	Disposable Endoscope Valve Sets	/
Regulation name	Endoscope and accessories	Endoscope and accessories	Same
Regulatory Class	II	II	Same
Product code	ODC	ODC	Same
Clinical characteristics			
Indications for use	The Disposable Endoscope Valve Sets 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. It includes an Air/Water Valve, a Suction Valve, a Biopsy Valve and an Auxiliary Water Connector. - 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. - 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. - Biopsy Valve: This unit is	The Disposable Endoscope Valve Sets 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. It includes an Air/Water Valve, a Suction Valve, a Biopsy Valve and an Auxiliary Water Connector. - 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. - 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. - Biopsy Valve: This unit is intended to be fitted to an	Same

Attribute	Subject device	Predicative device (K220884)	Discussion/ Conclusion
	intended to be fitted to an endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure. - Auxiliary Water Connector: This unit is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure. - Auxiliary Water Connector: This unit is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	
Compatible endoscopes	AF-DVS3-O, AF-DVS4-O, AF-BVC-O: Olympus® 140/ 160/ 180/ 190/ 240/ 260/ 290 Series GI Endoscope AF-DVS3-P, AF-DVS4-P, AF-BVC-P: Pentax® 90/ i10 GI Endoscope AF-DVS3-F, AF-DVS4-F, AF-BVC-F: Fujifilm® 700 Series GI Endoscope	SML002_LP01_AW: Olympus® 140/160/ 180/ 190/ 240/ 260/ 290 Series GI Endoscope SML001_PT01_AW: Pentax® 90/i10 GI Endoscope SML003_FJ01_AW: Fujifilm® 700 Series GI Endoscope	Same
General technological characteristics			
Device composition and specifications	AF-DVS3-O: Air/Water Valve+ Suction Valve+ Biopsy Valve AF-DVS4-O : Air/Water Valve+ Suction Valve+ Biopsy Valve+ Auxiliary Water Connector AF-BVC-O: Biopsy Valve	SML002: Air/Water Valve+ Suction Valve+ Biopsy Valve+ Auxiliary Water Connector	Same
	AF-DVS3-P: Air/Water Valve+ Suction Valve+ Biopsy Valve AF-DVS4-P: Air/Water Valve+ Suction Valve+ Biopsy Valve+ Auxiliary Water Connector AF-BVC-P: Biopsy Valve	SML001: Air/Water Valve+ Suction Valve+ Biopsy Valve	
	AF-DVS3-F: Air/Water Valve+ Suction Valve+ Biopsy Valve AF-DVS4-F: Air/Water Valve+ Suction Valve+ Biopsy Valve+ Auxiliary Water Connector AF-BVC-F: Biopsy Valve	SML003: Air/Water Valve+ Suction Valve+ Biopsy Valve	
Principle of Operation	Biopsy Valve: The Biopsy valve will close fitting with the forceps	Biopsy Valve: The Biopsy valve will close fitting with the forceps	Same

Attribute	Subject device	Predicative device (K220884)	Discussion/ Conclusion
	port to prevents gas and liquid from overflowing from the forceps port, the cross cutting on the surface can reduce friction between the instrument and the forceps port. Air/Water Valve: The principal axis of Air/Water valve is equipped with different sizes of sealing rings, which use spring to control advance and retreat, and control the water supply and air supply function of endoscope in endoscopic surgery. Suction Valve: The principal axis of Suction valve is equipped with different sizes of sealing rings, which use spring to control advance and retreat, and endoscope suction function in endoscopic surgery. Auxiliary Water Connector: The principal axis of Auxiliary Water Connector is equipped with sealing rings, which used to prevent leakage. One end is connected to an irrigation pump and the other to a pipe. It acts as a connector through which water passes.	port to prevents gas and liquid from overflowing from the forceps port, the cross cutting on the surface can reduce friction between the instrument and the forceps port. Air/Water Valve: The principal axis of Air/Water valve is equipped with different sizes of sealing rings, which use spring to control advance and retreat, and control the water supply and air supply function of endoscope in endoscopic surgery. Suction Valve: The principal axis of Suction valve is equipped with different sizes of sealing rings, which use spring to control advance and retreat, and endoscope suction function in endoscopic surgery. Auxiliary Water Connector: The principal axis of Auxiliary Water Connector is equipped with sealing rings, which used to prevent leakage. One end is connected to an irrigation pump and the other to a pipe. It acts as a connector through which water passes.	
Material	Air/Water Valve: ABS, Silicone Rubber, TPE, Stainless steel 304 Suction Valve: ABS, PC, Silicone Rubber, Stainless steel 304 Biopsy Valve: Silicone Rubber Water Connector: PC, Silicone Rubber	Air/Water Valve: ABS, Silicone Rubber, TPE, Stainless steel 304 Suction Valve: ABS, PC, Silicone Rubber, Stainless steel 304 Biopsy Valve: Silicone Rubber Water Connector: PC, Silicone Rubber	Same
Sterilization	Ethylene Oxide sterilization	Ethylene Oxide sterilization	Same

Attribute	Subject device	Predicative device (K220884)	Discussion/ Conclusion
Single use/reuse	For single use	For single use	Same
Shelf life	3 years	Not known	Different, see discussion 1

Discussion on differences between the subject device and the predicate device

Discussion 1: Although shelf life between the subject device and the predicate device is different, sterile process validation and shelf-life validation including performance test are performed on the subject device according to relevant standards, such differences will not affect the safety and effectiveness of the subject device.

VII. Summary of substantial equivalence discussion

Based on the above comparison table, the subject device and the predicate device are totally same on design features and performance specifications. There are no differences on device composition, specification and component material used as well on both devices. the only differences between the subject device and the predicate device are the sterile barrier system and other packages used for both devices. As all sterile process validation and shelf-life validation including performance test, transportation simulated test and biocompatibility tests are performed on the subject device according to relevant standards, such differences between the subject device and the predicate device do not affect the safety and effectiveness of the subject device when used as labeled.

VIII. Summary of Non-clinical Data

Non-clinical testing for Disposable Endoscope Valves Set was conducted to verify that the subject device met all design specifications, demonstrated safety and essential performance based on current applicable standards, and to demonstrate substantial equivalence to the predicate. The following tests were performed.

- Biocompatibility

The biocompatibility evaluation for the Disposable Endoscope Valves Set was conducted in accordance with the FDA guidance “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices - Part 1: Evaluation and testing

within a risk management process'" September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

- MTT Cytotoxicity Test: ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
- Skin Sensitization Test, Skin Irritation Test: ISO 10993-10:2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization
- Acute Systemic Toxicity Test and Pyrogen Test: ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

➢ Sterilization Validation

The EO sterilization of the Disposable Endoscope Valves Set has been validated according to the following applicable standards:

- ISO11135:2014+A1:2018 Sterilization of medical device- validation and routine control of ethylene oxide sterilization
- ISO 11737-2:2019 Sterilization of Medical Device-Microbiological methods-part 2: Tests of sterility performed in the validation of a sterilization process
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
- USP <85> Bacterial endotoxins test

➢ Shelf Life and Sterile Barrier System

Shelf Life and Sterile Barrier System of the Disposable Endoscope Valves Set has been validated according to the following applicable standards:

- ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO11607-1:2019 Packaging for terminally sterilized Medical Device Part 1: Requirement for materials，sterile barrier systems and packaging systems
- ISO11607-2:2019 Packaging for terminally sterilized Medical Device Part 2: Validation Requirement for forming, sealing and assembly process
- ASTM F 1929-15: Standard Test Method for Detecting Seal Leaks in Porous

Medical Packaging by Dye Penetration

- ASTM D 3078-02(2013): Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission
- DIN 58593-6: 2016 Sterilization – Sterile Supply – Part 6: Microbial Barrier Testing of Packaging Materials for Medical Devices Which Are to Be Sterilized
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM D4169-16 Standard practice for performance testing of shipping containers and systems (DC-13, Level II)

➢ Performance Data – Bench

The performance tests were implemented on both the subject device and the predicate device to demonstrate substantial equivalence according to the specific product specification as below listed:

Suction Valve:

- Endoscope Compatibility
- Depression Force
- Leakage Test
- Suction Flow

Air/Water Valve:

- Endoscope Compatibility
- Air flow rate
- Water flow rate
- Leakage Test
- Depression Force
- Backflow Performance Test

Biopsy Valve:

- Endoscope Compatibility
- Leakage Test

Auxiliary Water Connector:

- Endoscope Compatibility
- Leakage Test
- Water Flow Rate
- Backflow Performance Test

➢ Performance Data – Animal

N/A, no animal studies are available for the subject device.

IX. Summary of Clinical Data

N/A, no clinical studies are available for the subject device.

X. Conclusions

In conclusion, the technological characteristics, features, specifications, materials, principle of operation, and intended use of the subject device substantially equivalent to the predicate devices quoted above. The differences between the subjective device and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended. From the results of nonclinical testing described, it can be concluded that the subject device is substantially equivalent to the legally marketed predicate device.