January 17, 2023

SML Med-Tech Solutions Limited
% Cassie Lee, Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District
Guangzhou, Guangdong
CHINA

Re: K220884
Trade/Device Name: Disposable Endoscope Valve Sets
Regulation Number: 21 CFR 876.1500
Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: October 13, 2022
Received: October 14, 2022

Dear Cassie Lee:

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)*
K220884

Device Name
Disposable Endoscope Valve Sets

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 of K220884

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Date of the summary prepared: January 11, 2023

2. Submitter's Information

Sponsor Name: SML Med-Tech Solutions Limited
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Company: Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8200 6973
Email: regulatory@share-info.com

3. Subject Device Information

Type of 510(k): Traditional
Common Name: Endoscope and accessories
Classification Name: Endoscope Channel Accessory
Trade Name: Disposable Endoscope Valve Sets
Review Panel: Gastroenterology/Urology
Product Code: ODC
Regulation Number: 21 CFR 876.1500
Regulatory Class: Class II

4. Predicate Device Information

Sponsor: Wilson Instruments (SHA) Co., LTD

Common Name: Endoscope and accessories

Classification Name: Endoscope Channel Accessory

Trade Name: Disposable Endoscope Valves Set, Disposable Endoscope Valves Set B

510(k) Number: K200769

Review Panel: Gastroenterology/Urology

Product Code: ODC

Regulation Number: 21 CFR 876.1500

Regulatory Class: Class II

5. Device Description

The Disposable Endoscope Valve Sets 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 Valve Sets 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 Valve Sets 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 Valve Sets 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 Valve Sets 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.

6. Intended Use / 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 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.

7. Comparison to predicate device

Elements of Comparison	Subject Device	Predicate Device	Result
Company	SML Med-Tech Solutions Limited	Wilson Instruments (SHA) Co., LTD	--
510 (k) Number	K220884	K200769	--
Trade Name	Disposable Endoscope Valve Sets	Disposable Endoscope Valves Set, Disposable Endoscope Valves Set B	--
Product Code	ODC	ODC	Same
Common Name	Endoscope and accessories	Endoscope and accessories	Same
Classification Name	Endoscope Channel Accessory	Endoscope Channel Accessory	Same
Classification	Class II	Class II	Same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	Same
Comparison of Air/Water Valve			
Indications for use	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.	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.	Same
Compatible endoscopes	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	WS-VO-01: Olympus 140/160/180/190/240/260/290 series endoscopes WS-VP-01: PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series	Similar Note 1
Sterile	EO sterilization	EO sterilization	Same
Single Use	Yes	Yes	Same

Elements of Comparison	Subject Device	Predicate Device	Result
Material	ABS, Silicone Rubber, TPE, Stainless steel 304	WS-VO-01: SIR, ABS, TPE, Stainless steel 304 WS-VP-01: SIR, ABS, TPE, Stainless steel 304	Same
Environment of use	Hospitals/clinics	Hospitals/clinics	Same
Comparison of Suction Valve			
Indications for use	This unit is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air.	This unit is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air.	Same
Compatible endoscopes	SML002_LP01_SU, SML002_LP02_SU: Olympus® 140/ 160/ 180/ 190/ 240/ 260/290 Series GI Endoscope SML001_PT01_SU, SML001_PT02_SU, SML001_PT03_SU: Pentax® 90/ i10 GI Endoscope SML003_FJ01_SU, SML003_FJ02_SU: Fujifilm® 700 Series GI Endoscope	WS-VO-02: Olympus 140/160/180/190/240/260/290 series endoscopes WS-VP-02: PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series	Similar Note 1
Sterile	EO sterilization	EO sterilization	Same
Single Use	Yes	Yes	Same
Material	ABS, PC, Silicone Rubber, Stainless steel 304	WS-VO-02: SIR, ABS, TPE, Stainless steel 304, Stainless steel 17-4PH WS-VP-02: SIR, ABS, TPE, Stainless steel 304	Similar Note 2
Environment of use	Hospitals/clinics	Hospitals/clinics	Same
Comparison of Biopsy Valve			
Indications for use	This unit is intended to be fitted to	This unit is intended to be fitted	Same

Elements of Comparison	Subject Device	Predicate Device	Result
	an endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure.	to an endoscope biopsy port to prevent leakage of gases and body fluids during an endoscopic procedure.	
Compatible endoscopes	SML002_LP01_BP: Olympus® 140/ 160/ 180/ 190/ 240/ 260/290 Series GI Endoscope SML001_PT01_BP: Pentax® 90/ i10 GI Endoscope SML003_FJ01_BP: Fujifilm® 700 Series GI Endoscope	Olympus 140/160/180/190/240/260/290 series endoscopes	Similar Note 1
Sterile	EO sterilization	EO sterilization	Same
Single Use	Yes	Yes	Same
Material	Silicone Rubber	Silicon rubber	Similar Note 2
Environment of use	Hospitals/clinics	Hospitals/clinics	Same
Comparison of Water Connector			
Indications for use	This unit is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	This unit is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.	Same
Compatible endoscopes	SML002_LP01_AU: Olympus® 140/ 160/ 180/ 190/ 240/ 260/290 Series GI Endoscope SML001_PT01_AU: Pentax® 90/ i10 GI Endoscope SML003_FJ01_AU: Fujifilm® 700 Series GI Endoscope	Olympus 140/160/180/190/240/260/290 series endoscopes	Similar Note 1
Sterile	EO sterilization	EO sterilization	Same
Single Use	Yes	Yes	Same
Material	PC, Silicone Rubber	SIR, PVC, PC, Stainless	Similar

Elements of Comparison	Subject Device	Predicate Device	Result
		steel 303	Note 2
Environment of use	Hospitals/clinics	Hospitals/clinics	Same

Comparison in Detail(s):

Note 1:

Although the “Compatible endoscopes” of the subject device is a little different from the predicate device, the subject device is designed for intended use with the corresponding endoscopes mentioned and all the components of the subject device have good compatibility with the compatible endoscopes. So, the differences between the subject device and predicate device will not affect the safety and effectiveness.

Note 2:

Although the “Material” of the subject device is a little different from the predicate device, they all met the requirements of the ISO 10993 series biocompatibility standards. So, the differences between the subject device and predicate device will not affect the safety and effectiveness.

8. Test Summary

8.1 Summary of Non-Clinical Performance Testing

1) Performance

The SML Med-Tech Solutions Limited has performed bench testing to support substantial equivalence. The following tests were performed on the subject devices and predicate devices.

For Suction Valve SML001_PT01_SU, SML001_PT02_SU, SML001_PT03_SU, SML002_LP01_SU, SML002_LP02_SU, SML003_FJ01_SU, SML003_FJ02_SU:

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

For Air/Water Valve SML001_PT01_AW, SML002_LP01_AW, SML003_FJ01_AW:

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

For Biopsy Valve SML001_PT01_BP, SML002_LP01_BP / SML003_FJ01_BP:

- Endoscope Compatibility
- Leakage Test

For Auxiliary Water Connector SML001_PT01_AU, SML002_LP01_AU, SML003_FJ01_AU:

- Endoscope Compatibility
- Leakage Test
- Water flow rate
- Backflow Performance Test

2) Sterilization

All the subject devices are sold in sterile packages, like the predicate devices. The subject devices have been sterilized in a validated EO sterilization cycle. The EO sterilization cycle has a Sterility Assurance Level (SAL) of 10^{-6}. EO residuals on the components are below the maximum levels defined in ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide sterilization residuals.

3) Biocompatibility

The biocompatibility of the subject devices was conducted in accordance with the FDA guideline “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”. Biocompatibility testing is conducted on the subject device in accordance with the ISO 10993 standards. It included the following tests:

- In Vitro Cytotoxicity Test
- Skin sensitization Test
- Irritation or intracutaneous reactivity Test

The subject devices are classified as surface devices with mucosal membrane contact for a limited duration (not more than 24 hours). The test result shows that the subject devices are biocompatible.

4) Package integrity

The package integrity test of the subject devices has been established to study whether the packaging will maintain a sterile barrier for the entirety of the proposed shelf life, after simulated distribution. And visual inspection, seal strength test (ASTM F88/F88M-2015), and dye penetration testing (ASTM F1929-2015) have been conducted on the subject device before aging products, and products have undergone accelerated aging followed by simulated distribution. The test results show that the subject devices maintain a sterile barrier for the entirety of the proposed shelf life, after simulated distribution.

8.2 Summary of Clinical Performance Test

No clinical study is included in this submission.

9. Final Conclusion：

The subject device Disposable Endoscope Valve Sets is substantially equivalent to the predicate device.