September 8, 2022

Changzhou Endoclean Medical Device Co., Ltd.
Wang Qi, QA Manager
West Side of 4th Floor, Building E2, No.9 Changyang Road
Changzhou, Jiangsu 213149
CHINA

Re: K221331
Trade/Device Name: Disposable Endoscope Valves System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODC
Dated: August 9, 2022
Received: August 10, 2022

Dear Wang Qi:

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, 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)*
K221331

Device Name
Disposable Endoscope Valves System

Indications for Use *(Describe)*
The Disposable Endoscope Valves System includes an air/water valve, a suction valve, a biopsy valve and a water connector.
Disposable Biopsy Valve, it is intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of biomaterial during an endoscopic procedure.
Disposable Air/Water Valve, it is intended to be fitted to an endoscope Air/water channel to enable the operator to control inflow of medical gases and water.
Disposable Suction Valve, it is intended to be fitted to an endoscope suction channel to enable the operator to control suction.
Water Jet Connector, it is intended to prevent liquid backflow when providing sterile water to the endoscope during endoscopic surgery.

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-K221331

I. Submitter

Changzhou Endoclean Medical Device Co., Ltd.

West Side of 4th Floor, Building E2, No.9 Changyang Road, West Taihu Science and Technology Industrial Park, Wujin District, 213149 Changzhou City, Jiangsu Province, China

Establishment Registration Number: 3021349683

Contact person: Ms Wang Qi

Position: QA Manager
Tel.: +86-0519-68213060
E-mail: lena@endocleanmedical.com

Preparation date: Aug. 09, 2022

II. Proposed Device

Device Trade Name: Disposable Endoscope Valves System
Common name: Endoscope Channel Accessory
Regulation Number: 21 CFR 876.1500
Regulatory Class: Class II
Product code: ODC
Review Panel: Gastroenterology/Urology

Table 1 Valves included in this submission

Valves name	Classification name	Regulation number	Classification
Biopsy Valve	ODC- endoscope channel accessory	876.1500	Class II
Air/Water Valve;	ODC- endoscope channel accessory	876.1500	Class II
Suction Valve	ODC- endoscope channel accessory	876.1500	Class II
Water Jet Connector	ODC- endoscope channel accessory	876.1500	Class II

III. Predicate Devices

a. 510(k) Number: K090851
Common name: Endoscopes and accessories
Classification: 21 CFR 876.1500
Product Code: ODC
Trade name: DEFENDO™ Biopsy Valve for Olympus and Fujinon Endoscopes
DEFENDO™ Biopsy Valve for Pentax Endoscopes
Manufacturer: Medivators Inc formerly Byrne Medical

b. 510(k) Number: K200769
Product Code: ODC
Classification: 21 CFR 876.1500
Trade Name: Disposable Endoscope Valves Set,
Disposable Endoscope Valves Set B
Manufacturer: Wilson Instruments (SHA) Co., LTD.

c. 510(k) Number: K102409
Product Code: ODC
Classification: 21 CFR 876.1500
Trade Name: DEFENDO™ Disposable Air/Water Valve for GI Endoscopes
Manufacturer: Medivators Inc formerly Byrne Medical

IV. Device description

The Endoscope Valves System are used to fit to multiple endoscopes working channels/ports to enable an endoscope operator control the function of the working channels/ports and prevent retrograde flow of the fluids, gases, and other materials.

It includes an air/water valve, a suction valve, a biopsy valve and a water connector. All valves are single-use device and packed individually in a sealed package or different types of valves products is packed into one package units. The valves are manufactured for use with OLYMPUS Endoscope Series, FUJIFILM Endoscope 700 Series, and Pentax 90 series endoscope. Some valve may be sold as both sterile and non-sterile.

V. Indication for use

The Disposable Endoscope Valves System includes an air/water valve, a suction valve, a biopsy valve, and a water connector.

Disposable Biopsy Valve, it is intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of biomaterial during an endoscopic procedure.

Disposable Air/Water Valve, it is intended to be fitted to an endoscope Air/water channel to enable the operator to control inflow of medical gases and water.

Disposable Suction Valve, it is intended to be fitted to an endoscope suction channel to enable the operator to control suction.

Water Jet Connector, it is intended to prevent liquid backflow when providing sterile water to the endoscope during endoscopic surgery.

VI. Comparison of technological characteristics with the predicate devices

Table 2 Substantial equivalence discussion – Biopsy Valve

Item	**Proposed device**	**Predicate device** (K090851)	**Discussion**
Product name	Disposable Biopsy Valves	Disposable Biopsy Valves	-
Product Code	ODC	ODC	same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	same
Class	Class II	Class II	same
Indications for Use	The Biopsy Valves is intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of bio material during an endoscopic procedure.	The DEFENDO™ Disposable Biopsy Valve is indicated for covering the endoscope biopsy port during an endoscopy procedure. The valve provides access for endoscopic device passage and exchange, helps maintain sufflation and minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure.	similar
Compatible endoscopes	EDKN-004001/ EDKN-004006/ EDKN-004012:	Olympus® Endoscopes & Fujifilm® Endoscopes	Similar[1]

	OLYMPUS Endoscope Series 140/160/180/190/240/ 260/290; & FUJIFILM Endoscope 700 Series; EDKN-004009: Pentax Endoscope 90 Series;	(100301) Pentax® Endoscopes (100302)	
Environment of Use	Hospital and/or clinics	Hospital and/or clinics	same
Material	Thermoplastic elastomer	Silicone	Different[2]
Single for Use	Yes	Yes	same
Sterilization	EO	EO	same
Shelf life	3 years	3 years	same

Table 3 Substantial equivalence discussion –Air/Water Valves

Item	**Proposed device**	**Predicate device** (K102409)	**Discussion**
Product name	Disposable Air/Water Valves	DEFENDO™ Disposable Air/Water Valve	-
Product Code	ODC	ODC	same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	same
Class	Class II	Class II	same
Indications for Use	The Disposable Air/Water Valve, it is intended to be fitted to an endoscope Air/water channel to enable the operator to control inflow of medical gases and water.	The Single Use Air/Water Valve is intended to be used to control the air/water function on an endoscope during a GI endoscopic procedure.	similar
Compatible endoscopes	EDKN-004007: OLYMPUS Endoscope Series	OLYMPUS Endoscope Series	Similar[1]

	140/160/180/190/240/ 260/290; EDKN-004010: Pentax Endoscope 90 Series; EDKN-004013: FUJIFILM Endoscope 700 Series;	140/160/180/240/ 260;	
Environment of Use	Hospital and/or clinics	Hospital and/or clinics	same
Material	Silicone, ABS, TPE, SUS 303	PC, TPE, Stainless steel 304	Similar[2]
Single for Use	Yes	Yes	same
Sterilization	EO	EO	same
Shelf life	3 years	3 years	same

Table 4 Substantial equivalence discussion –Suction Valve

Item	**Proposed device**	**Predicate device** (K200769)	**Discussion**
Product name	Disposable Suction Valves	Disposable Suction Valves	-
Product Code	ODC	ODC	same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	same
Class	Class II	Class II	same
Indications for Use	The Disposable Suction Valve is intended to be fitted to an endoscope suction channel to enable the operator to control suction.	The device is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air.	similar
Compatible endoscopes	EDKN-004008: OLYMPUS Endoscope Series 140/160/180/190/240/ 260/290;	WS-VO-02: Olympus 140/160/180/190/240/260/290 series endoscopes	Similar[1]

	EDKN-004011: Pentax Endoscope 90 Series; EDKN-004014: FUJIFILM Endoscope 700 Series;	WS-VP-02: PENTAX GI Video Endoscope 90K/90i Series; K10/i10 Series	
Environment of Use	Hospital and/or clinics	Hospital and/or clinics	same
Material	SUS 303, ABS, TPE, NBR,	WS-VO-02: SIR, ABS, TPE, Stainless steel 304, Stainless steel 17-4PH; WS-VP-02: SIR, ABS, TPE, Stainless steel 304	Similar[2]
Single for Use	Yes	Yes	same
Sterilization	EO	EO	same
Shelf life	3 years	3 years	same

Table 5 Substantial equivalence discussion –Water Jet Connector

Item	**Proposed device**	**Predicate device** (K200769)	**Discussion**
Product name	Disposable Water Jet Connector	Disposable Endoscope Water Connectors	-
Product Code	ODC	ODC	same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	same
Class	Class II	Class II	same
Indications for Use	The Water Jet Connector is intended to prevent liquid backflow when providing sterile water to the endoscope during endoscopic surgery.	The device is intended to be fitted to an endoscope suction channel to control the operations of suction, whilst preventing inflow of air.	similar

Compatible endoscopes	EDKN-004002& EDKN-004003: OLYMPUS Endoscope Series 140/160/180/190/240/ 260/290; EDKN-004004: Pentax Endoscope 90 Series; EDKN-004005: FUJIFILM Endoscope 700 Series;	Olympus 140/160/180/190/240/260/290 series endoscopes	Similar[1]
Environment of Use	Hospital and/or clinics	Hospital and/or clinics	same
Material	PC, TPR, NBR, SUS 303	SIR, PVC, PC, Stainless steel 303	Similar[2]
Single for Use	Yes	Yes	same
Sterilization	EO	EO	same
Shelf life	3 years	3 years	same

[1] The proposed device has different compatibility scope than predicate device, for this different, the performance testing to the proposed device has included compatibility testing to all compatible endoscopes claimed, the testing results shown that the proposed devices are compatibility with all endoscopes claimed. So, this different does not affect the safety and effectiveness of proposed device.

[2] The difference in the materials and colors does not raise additional questions for safety and effectiveness of the device. The biocompatibility evaluation test of the subject devices has been performed on the final finished device which includes all construction materials and color additives. The test results show pass the requirements.

VII. Non-Clinical Testing

The non-clinical tests were conducted to verify that the proposed device met all design specifications as was substantial equivalence to the predicate device.

Biocompatibility testing

Biocompatibility of the Disposable Endoscope Valves System were evaluated in

accordance with ISO 10993-1:2009 for the body contact category of “Surface – Mucosal Membrane” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended: Cytotoxicity, Irritation and Intracutaneous Reactivity. All evaluation acceptance criteria were met.

Performance testing

The following performance testing was performed on the proposed device:

Biopsy Valves

- Sealing performance test
- Strength of assemble

Air/Water Valves

- Air leakage test
- Water flow test

Suction Valves

- Suction flow test

Water Jet Connectors

- Positive pressure performance test
- Backpressure performance test
- Backflow Prevention Test

In addition, the compatibility testing was conducted to support that the proposed device is compatibility with commercially endoscopes (i.e., Pentax, Olympus, and Fujifilm Gastrointestinal Endoscopes).

Sterilization and Shelf-life testing

The sterilization method has been validated to ISO11135, which has thereby determined the routine control and monitoring parameters. 3-year shelf-life of the device has been evaluated by accelerated aging test.

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.