November 29, 2023

Changzhou Endoclean Medical Device Co., Ltd.
Qi Wang
QA Manager
West Side of 4th Floor, Bldg E2, No.9 Changyang Rd., West
Taihu Science and Technology Industrial Park, Wujin Disrict
Changzhou, Jiangsu 213149
China

Re: K232244
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: October 30, 2023
Received: October 30, 2023

Dear Qi Wang:

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.

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, PhD
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
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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.*

Submission Number *(if known)*

K232244

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, a water connector, AW channel cleaning Adapter and suction cleaning adapter
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 bio material 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.
Disposable AW Channel Cleaning Adapter, it is attached to the air/water cylinder of the endoscope, used for the air water channel pre-cleaning after the procedure.
Disposable Suction Cleaning Adapter also as one of accessories of the pre-cleaning endoscopic irrigation. The one end can be connected to the biopsy channel, the other end be connected to the water container. It is used to aspirate reprocessing fluids through the instrument channel port of the endoscope.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary

## I. Submitter

Changzhou Endoclean Medical Device Co., Ltd.
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Preparation date:July 11, 2023

### Submission Correspondent

Ms. Kyra Kang
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E-mail: kyra.kang@landlink-health.com

## 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 |

## III. Predicate Devices

| | |
|---|---|
| 510(k) Number: | K131780 |
| Trade name: | EVIS EXERA III VIDEO SYSTEM |
| Common name: | Endoscope Channel Accessory |
| Classification: | Class II |
| Product Code: | FDF |
| Manufacturer | OLYMPUS MEDICAL SYSTEMS CORP. |

## IV. Device description

The Endoscope Valves Systemare used to fit to multiple endoscope working channels/ports to enable anendoscope 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, a water connector, AW channel cleaning Adapterand suction cleaning adapter.All valvesare 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 valvemay besold as both sterileand non-sterile.

## V. Indication for use

Disposable AW Channel Cleaning Adapter, it is attached to the air/water cylinder of the endoscope, used for the air water channel pre-cleaning after the procedure.

Disposable Suction Cleaning Adapter also as one of accessories of the pre-cleaning endoscopic irrigation. The one end can be connected to the biopsy channel, the other end be connected to the water container. It is used to aspirate reprocessing fluids through the instrument channel port of the endoscope.

## VI. Comparison of technological characteristics with the predicate devices

Table 1 General Comparison of AW Channel Cleaning Adapter

| Characteristics | Proposed device | Predicate device | Discussion |
|---|---|---|---|
| Product name | AW Channel Cleaning Adapter | AW channel cleaning adapter | Same |
| Indications For Use | Disposable AW Channel Cleaning Adapter, it is attached to the air/water cylinder of the endoscope, used for the air water channel pre-cleaning after the procedure. | During precleaning of the endoscope, the AW channel cleaning adapter is attached to the air/water cylinder of the endoscope. When the button of the adapter is depressed, the water in the water container is fed through the air/ water nozzle of the endoscope to clean the nozzle and air/water channels of the endoscope. Air is continuously fed through the air/water | Similar |

| | | | |
|---|---|---|---|
| | | channels when the button is not depressed. | |
| Product Code | ODC | FDF | Different |
| Regulation Number | 21 CFR 876.1500 | 21 CFR 876.1500 | Same |
| Class | II | II | Same |
| Environment of use | Hospital and/or clinics | Hospital and/or clinics | Same |
| Compatible endoscopes | EDKN-004007: OLYMPUS Endoscope Series 140/160/180/190/240/ 260/290; EDKN-004010: Pentax Endoscope 90 Series; EDKN-004013: FUJIFILM Endoscope 700 Series; | OLYMPUS Endoscope Series 140/160/180/240/ 260; | Similar[1] |
| Material | ABS, SUS 303, TPE, Silicone, PP | ABS, SUS 303, TPE, Silicone, PP | Same |
| Single for Use | Yes | Yes | Same |
| Sterilization | EO | EO | Same |
| Shelf life | 3 years | 3 years | Same |

Table 2 General Comparison of Suction Cleaning Adapter

| **Characteristics** | **Proposed device** | **Predicate device** | **Discussion** |
|---|---|---|---|
| Product | Suction Cleaning Adapter | Suction Cleaning Adapter | Same |

| | | | |
|---|---|---|---|
| name | | | |
| Indications For Use | Disposable Suction Cleaning Adapter also as one of accessories of the pre-cleaning endoscopic irrigation. The one end can be connected to the biopsy channel, the other end be connected to the water container. It is used to aspirate reprocessing fluids through the instrument channel port of the endoscope. | The suction cleaning adapter is used to aspirate reprocessing fluids through the instrument channel port of the endoscope. | Same |
| Product Code | ODC | FDF | Different |
| Regulation Number | 21 CFR 876.1500 | 21 CFR 876.1500 | Same |
| Class | II | 11 | Same |
| Environment of use | Hospital and/or clinics | Hospital and/or clinics | Same |
| Compatible endoscopes | EDKN-004007: OLYMPUS Endoscope Series 140/160/180/190/240/ 260/290; EDKN-004010: Pentax Endoscope 90 Series; EDKN-004013: FUJIFILM Endoscope 700 Series; | OLYMPUS Endoscope Series 140/160/180/240/ 260; | Similar[1] |
| Material | Silicone, ABS,PVC | Silicone, ABS,PVC | Silicone, ABS,PVC |
| 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.

**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(< 24hours)”. 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:

AW Channel CleaningAdapter
- Water flow test
- Side by side test

Suction CleaningAdapter
- Suction flow test
- Side by side test

In addition, the compatibility testing was conduct to support that the proposed device are 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 proposeddevice has the same indication for useand 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.