October 7, 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: K221310
Trade/Device Name: Endoscopic Clean Connecting Tubes, Endoscopic CO2 Source Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX, FCX
Dated: September 1, 2022
Received: September 6, 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221310

Device Name
Endoscopic Clean Connecting Tubes, Endoscopic CO2 Source Tubing

Indications for Use *(Describe)*
The Endoscopic Clean Connecting Tubes includes five subsets as below, they are intended to o provide sterile water and/ or CO2 and/ or air to an endoscope during gastrointestinal endoscopic procedure. These devices are intended to be used by healthcare professional only. This device is intended to be used for not more than 24 hours. It is a 24-hour multi-patient use device. It is supplied in sterile.

Irrigation Tube
The Irrigation Tube (tube and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

Clean Cap
Clean cap is intended to be used with an air or CO2 source and / or pump along with a sterile water source to supply air or CO2 and sterile water to gastrointestinal endoscope during endoscopic procedures.

Clean Cap with CO2 Source Tube
Clean cap with CO2 source tube is intended to be used with CO2 source along with a sterile water source to supply CO2 and sterile water to gastrointestinal endoscope during endoscopic procedures.

Hybrid Irrigation Tubing
The Hybrid irrigation tubing (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO2 (via a CO2 supply) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump.

Hybrid Irrigation Tubing With CO2 source tube
The Hybrid Irrigation Tubing with CO2 Source Tube (tubing and accessories to accommodate various GI endoscopes, irrigation pumps and CO2 source) is intended to provide irrigation via sterile water when used in conjunction with an irrigation pump, and to supply CO2 along with sterile water during GI endoscopic procedures.

Endoscopic CO2 Source Tubing is intended to be used with a CO2 insufflator along with Clean Cap or Hybrid Irrigation Tubing to supply CO2 to a GI endoscope during GI endoscopic procedures.

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

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: Sep 21, 2022

II. Proposed Device

Device Trade Name:	Endoscopic Clean Connecting Tubes Endoscopic CO2 Source Tubing
Common name:	Endoscopic irrigation/suction system Insufflator, automatic carbon-dioxide for endoscope
Regulation Number:	21 CFR 876.1500
Regulatory Class:	Class II
Product code:	OCX
Subsequent Product Code	FCX
Review Panel:	Gastroenterology/Urology

The Gastroenterology/Urology devices panel has classified Endoscopic Irrigation/Suction System as Class II under 21 CFR §876.1500. OCX is the product code that has been assigned for Endoscopic Clean Connecting Tubes. FCX is the product code that has been assigned for Endoscopic CO_2 Source Tubing.

III. Predicate Devices

510(k) Number: K203350

Trade name: Endoscopic tubing kit
Property Name: ENDOtube
Classification: Class II
Product Code: OCX
Manufacturer NISSHA MEDICAL TECHNOLOGIES SAS

IV. Device description

The proposed device includes two (2) categories:

- Endoscopic Clean Connecting Tubes
- Endoscopic CO_2 Source Tubing

The proposed device, Endoscopic Clean Connecting Tubes, is to connect an air/ CO_2 source, a sterile water source (water bottle), and an endoscope to supply air/ CO_2 and water during gastrointestinal endoscopic procedures. This device is intended to be used for not more than 24 hours. It is a 24-hour multi-patient use device. It is supplied in sterile.

The Endoscopic Clean Connecting Tubes includes five (5) subsets：

- Irrigation Tube;
- Clean Cap
- Clean Cap with CO_2 Source Tube
- Hybrid Irrigation Tubing
- Hybrid Irrigation Tubing With CO_2 source tube

The Endoscopic CO_2 Source Tubing is designed to be attached to the air/water bottle tubing and the outlet of the CO_2 insufflator to provide irrigation and CO_2 insufflation through the air/water channel to the distal end of endoscope. It is composed of one female luer connector, one male luer connector, one rigid tube and air/gas filter. The air/gas filter can filter particulates from the CO_2 source and keeps fluid from flowing into the CO_2 Source.

The Endoscopic Clean Connecting Tubes and CO_2 Source Tubing are provided sterile. The both device is sterilized by EO and the shelf life is three (3) years.

V. Indication for use

The Endoscopic Clean Connecting Tubes includes five subsets as below, they are intended to o provide sterile water and/or CO_2 and/ or air to an endoscope during gastrointestinal endoscopic procedure. These devices are intended to be used by

healthcare professional only. This device is intended to be used for not more than 24 hours. It is a 24-hour multi-patient use device. It is supplied in sterile.

Irrigation Tube
The Irrigation Tube (tube and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

Clean Cap
Clean cap is intended to be used with an air or CO_2 source and / or pump along with a sterile water source to supply air or CO_2 and sterile water to gastrointestinal endoscope during endoscopic procedures.

Clean Cap with CO_2 Source Tube
Clean cap with CO_2 source tube is intended to be used with CO_2 source along with a sterile water source to supply CO_2 and sterile water to gastrointestinal endoscope during endoscopic procedures.

Hybrid Irrigation Tubing
The Hybrid irrigation tubing (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via sterile water and to supply air (via an air pump) or CO_2 (via a CO_2 supply) along with sterile water during GI endoscopic procedures when used in conjunction with an irrigation pump.

Hybrid Irrigation Tubing With CO_2 source tube
The Hybrid Irrigation Tubing with CO_2 Source Tube (tubing and accessories to accommodate various GI endoscopes, irrigation pumps and CO_2 source) is intended to provide irrigation via sterile water when used in conjunction with an irrigation pump, and to supply CO_2 along with sterile water during GI endoscopic procedures.

Endoscopic CO_2 Source Tubing is intended to be used with a CO_2 insufflator along with Clean Cap or Hybrid Irrigation Tubing to supply CO_2 to a GI endoscope during GI endoscopic procedures.

VI. Comparison of technological characteristics with the predicate devices

Table 1 summaries the proposed device technological characteristics with compared to the predicate device from ENDOtube under K203350.

Table 1 Technological Characteristics Comparison

Item	Proposed device	Predicate device (K203350)	Discussion
Product name	Endoscopic Clean Connecting Tubes Endoscopic CO_2 Source Tubing	ENDOtube	same
Product Code	OCX, FCX	OCX	same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	same
Class	Class II	Class II	same
Indications*	The Endoscopic Clean Connecting Tubes are intended to o provide sterile water and/or CO_2 and/ or air to an endoscope during gastrointestinal endoscopic procedure. These devices are intended to be used by healthcare professional only. This device is intended to be used for not more than 24 hours. It is a 24-hour multi-patient use device. It is supplied in sterile. The Endoscopic CO_2 Source Tubing is intended to be used with a carbon dioxide (CO_2) source with the purpose of supplying CO_2 to the endoscope during endoscopic procedures. This device is intended to be used for not more than 24 hours. It is a 24-hour multi-patient use device.	The ENDOtube devices are a combination of tubes, fittings and valves intended to provide sterile water and/or CO_2 and/ or air to an endoscope during gastrointestinal endoscopic procedure. These devices are intended to be used by healthcare professional only. In procedure room, all ENDOtube devices are 24 hours use disposable products except the one-way valves which are single use products and the insufflation connectors which are multiple patient use.	similar

Environment of use	Hospital and/or clinics	Hospital and/or clinics	same
Materials	PC, PVC, POM, SUS303，TPE，NBR，Silicone，PE	PVC，Silicone，SAN/ABS，TPU	similar[1]
Duration of Use	Less than 24 hours	Less than 24 hours	same
Endoscope column compatibility	Olympus Endoscopes 140/160/180/190/240/260/290；	OLYMPUS® GI endoscopes 140, 160, 180 and 190；	similar[2]
	PENTAX 90 series endoscopes；	PENTAX® GI endoscopes；	
	FUJIFILM 500/600/700 endoscopes；	FUJIFILM® GI 500/600 series and 700 series endoscopes	
Irrigation peristatic pump compatibility	Olympus AFU-100, Olympus OFP, Olympus OFP-2 Medivators EGP-100, ERBE EIP2 or Endotechnik Irrigation Units	OLYMPUS®, Erbe®, EMED®	
Sterile water bottle compatibility	B.Braun, Fresenius, Asia-Pacific Baxter	Not provided in 510(k) Summary	
Sterilization	EO	EO	same
Shelf life	3 years	2 years	similar[3]
Biocompatibility	Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards	same

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

[2] The compatibility testing was conducted to support that proposed device can able to compatible with claimed various endoscopes, irrigation pumps and sterile water bottle.

[3] The shelf life of the proposed device is 3 years, which is longer than the predicated device. The determined based on accelerated aging study. The result of demonstrated that the packaging was able to maintains sterility of the sterilized finished device during its shelf life of 3 years.

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 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 performance testing was conducted for the performance of water flow rate, water and air leakage, endoscopy compatibility, irrigation peristatic pump compatibility and sterile compatibility etc. These testing demonstrated that the device can able to achieve its functional performance.

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the similar indications 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.