September 8, 2023

Zhejiang Chuangxiang Medical Technology Co., LTD.
Lucius Long
RA Manager
Room 101,201,301,401,501, Building 50, No.650 Hongfeng Road
Donghu Street, Yuhang District
Hangzhou, Zhejiang Province 311100
China

Re: K231471
Trade/Device Name: Air/Water Bottle Tubing, CO2 Source Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX, FCX
Dated: August 10, 2023
Received: August 10, 2023

Dear Lucius Long:

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)*

K231471

Device Name
Air/Water Bottle Tubing, CO2 Source Tubing

Indications for Use *(Describe)*

The Air/Water Bottle Tubing is to connect an air/CO2 source, a sterile water source (water bottle), and an endoscope to supply air/CO2 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.

The CO2 Source Tubing is intended to be used with a carbon dioxide (CO2) source with the purpose of supplying CO2 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.

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.

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Zhejiang Chuangxiang Medical Technology Co.,LTD.

Section 5 510(k) Summary(21CFR 807.92)

1. Submitter's information

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2. Sponsor contact

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3. Date of Submission

09-Aug- 2023

4. Device Identification

Trade/Device Name:Air/Water Bottle Tubing
Regulation name: Endoscope and accessories
Regulation class: II
Regulation number: 876.1500
Panel: Gastroenterology/Urology
Product code: OCX
Product Code Name: Endoscopic Irrigation/Suction System

Trade/Device Name: CO_2 Source Tubing
Regulation name: Endoscope and accessories
Regulation class: II
Regulation number: 876.1500
Panel: Gastroenterology/Urology
Product code: FCX
Product Code Name: Insufflator, Automatic Carbon-Dioxide For Endoscope

5. Predicative device identification

510(k) Number: K093665
Device 1 Name: Endo SmartCap™ Tubing

Product Code: FAJ
510(k) Number: K093665
Device 2 Name: Endo SmartCap™ CO_2 Source Tubing
Product Code: FAJ

6. Device description

The proposed device includes two (2) categories:
- Air/Water Bottle Tubing
- CO_2 Source Tubing

The Air/Water Bottle Tubing and CO_2 Source Tubing are intended for 24-hour multi-patient use. Air/water bottle tubing is supplied in sterile and CO_2 Source Tubing is supplied in non-sterile.

6.1 The Air/Water Bottle Tubing

The Air/Water Bottle Tubing is manufactured for use in conjunction with a sterile water bottle, and together with OLYMPUS®140/240, 160/260, 180/280, 190/290 series endoscopes. The Air/Water Bottle Tubing is individually packed in sealed package, sold as a sterile device. The Air/Water Bottle Tubing is designed to be attached to the air/water port of the endoscopes to provide irrigation through the air/water channel to the distal end of endoscope.

There are two types of the device Air/Water Bottle Tubing provided by the manufacturer, such as type A and type B. Type B has an additional air extended tubing but type A does not. The clinician selects the appropriate model according to the actual clinical needs.

6.2 The CO_2 Source Tubing

The CO_2 Source Tubing is manufactured for use in conjunction with air/water bottle tubing and CO_2 insufflator. The CO_2 Source tubing is individually packed in a sealed package, and sold as a non-sterile device. The 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.

7. Indications for Use

The Air/Water Bottle Tubing 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.

The 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.

8. Technological Characteristics:

Table 1 and 2 summarize the technological characteristics of the Air/Water Bottle Tubing and CO_2 Source Tubing compared to the predicate device.

Table 1 Summary of design, features and principles of operation between the technological characteristics of the Air/Water Bottle Tubing compared to the predicate devices.

Item	Proposed device	Predicate device	Comparison to Predicate Devices
Device name	Air/Water Bottle Tubing	Endo SmartCap™ Tubing	N/A
K number	/	K093665	N/A
Manufacturer	Zhejiang Chuangxiang Medical Technology Co., LTD.	Medivators, Inc	N/A
Product code	OCX	FAJ	N/A
Regulation No.	876.1500	876.1500	Same
Regulatory Classification	II	II	Same
Regulation Description	Endoscope and accessories	Endoscope and accessories	Same

Indications for Use	The Air/Water Bottle Tubing is to connect an air/CO2 source, a sterile water source (water bottle), and an endoscope to supply air/CO2 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.	Endo SmartCap™ Tubing 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 an gastrointestinal endoscope during endoscopic procedures.	Substantial Equivalent
Compatibility	OLYMPUS®140/240, 160/260, 180/280, 190/290 series GI endoscopes	OLYMPUS®140/240, 160/260, 180/280, 190/290 series GI endoscopes	Same
Materials	Polyvinyl Chloride, Silicone,Polycarbonate, Nickel plated brass, Polyoxymethylene, MABS, Polyformaldehyde Resin, Styrene Acrylonitrile, Styrene Acrylonitrile	Methyl methacrylate-acrylonitrile-butadiene-styrene copolymer, Polycarbonate, Polyethylene, Polyvinyl Chloride, Thermoplastic Elastomer, Nitrile Butadiene Rubber	Substantial Equivalent
Environment of Use	Hospital and or clinics	Hospital and or clinics	Same
Sterilization	EO gas	EO gas	Same
Packaging	Each model packed separately in a seal pouched	Each model packed separately in a seal pouched	Same
Manufacturing method	Injection molding	Injection molding	Same
Shelf Life	Three years (36months)	Three years (36months)	Same

Table 2 Summary of design, features and principles of operation between the technological characteristics of the CO_2 Source Tubing compared to the predicate devices.

Item	Proposed device	Predicate device	Comparison to Predicate Devices

Device name	CO_2 Source Tubing	Endo SmartCap™ CO_2Source Tubing	N/A
K number	/	K093665	N/A
Manufacturer	Zhejiang Chuangxiang Medical Technology Co., LTD.	Medivators, Inc	N/A
Product code	FCX	FAJ	N/A
Classification	II	II	Same
Regulation No.	876.1500	876.1500	Same
Regulation Description	Endoscope and accessories	Endoscope and accessories	Same
Supplied Sterile	No	No	Same
Supplied Sterile	No	No	Same
Indications for Use	The 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.	Endo SmartCap™ CO_2 Source Tubing with Luer Input is intended to be used with a CO_2 insufflator along with Endo SmartCap™ Irrigation Tubing or ENDOGATOR™ Hybrid Irrigation Tubing to supply CO_2 to a GI endoscope during GI endoscopic procedures	Substantial Equivalent
Environment of Use	Hospital and or clinics	Hospital and or clinics	Same
Materials	Polyvinyl Chloride, Polycarbonate, Polypropylene, Polytetrafluorethylene	Polycarbonate, Polyvinyl Chloride, high impact polystyrene, Polyethylene terephthalate, polytetrafluoroethylene	Substantial Equivalent
Packaging	Each model packed separately in a seal pouched	Each model packed separately in a seal pouched	Same

Manufacturing method	Injection molding	Injection molding	Same
Shelf Life	Three years (36months)	Three years (36months)	Same

9. Non-clinical Performance Data

The bench testing was performed to support substantial equivalence. The following testing were performed on samples from initial lots, including sterilization.

9.1 Performance Test

9.1.1 Air/Water Bottle Tubing

9.1.1.1 Assembling Integrity
9.1.1.2 Two-Way Valve Integrity
9.1.1.3 Air Flow Test
9.1.1.4 Water Flow Test
9.1.1.5 Air Leak Test
9.1.1.6 Flow Clamp Test
9.1.1.7 Water Backflow Test
9.1.1.8 24-Hour Use Test
9.1.1.9 Endoscope Compatibility
9.1.1.10 Compatibility With Bottle

9.1.2 CO_2 Source Tubing

9.1.2.1 Assembling Integrity
9.1.2.2 Co_2 Delivery Test
9.1.2.3 Water Delivery Test
9.1.2.4 Air Leak Test
9.1.2.5 Compatibility With Air/Water Bottle Tubing

9.2 Sterilization

The Air/Water Bottle Tubing is sold in a sterile package, like the predicate devices. The proposed 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. The Air/Water Bottle Tubing, and the predicate devices, are not labeled as pyrogen-free because they do not have any blood or cerebrospinal fluid contact.

The CO_2 Source Tubing is supplied in non-sterile.

9.3. Shelf Life

The Air/Water Bottle Tubing and the CO_2 Source Tubing both have three (3) years shelf life, which have been validated in an accelerated testing according to ASTM F1980-21 and the requirements on packaging for terminally sterilized medical device per ISO 11607-1 Second Edition 2019-02 and ISO 11607-2 Second Edition 2019-02 have also met. The testing successfully demonstrated essential performance was achieved before and after the shelf life testing.

9.4. Biocompatibility

Biocompatibility testing has been performed to show that all patient contacting materials meet applicable biocompatibility standards per ISO 10993-1:2009 and 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”.it included the following tests:

Acute Systemic Toxicity Test,
In Vitro Cytotoxicity Test,
Skin Sensitization Test
and Intracutraneous Reactivity

The Air/Water Bottle Tubing and the CO_2 Source Tubing are classified as surface device with mucosal membrane contact for a limited duration (not more than 24 hours), the test result show that the proposed devices are biocompatible.

10. Clinical Testing

Similar devices have been on the market for many years with proven safety and effectiveness for the use of the device. These devices have no direct patient contact. Based on this history and the use of the device, clinical testing was not necessary to support substantial equivalence data. The non-clinical testing performed supports the safety and effectiveness of the devices and provides data to show substantial equivalence to the predicate device.

11. Conclusions

The Air/Water Bottle Tubing and CO_2 Source Tubing have the same intended use as the predicate devices.

Based on the technological characteristics and overall performance of the devices in bench testing, Chuangxiang believes that no significant differences exist between the proposed devices and the predicate devices.

The proposed devices don’t raise any new issues of safety and effectiveness.

From a clinical perspective and comparing design specifications, the proposed device Air/Water Bottle Tubing and CO_2 Source Tubing, and the predicate device are substantially equivalent.