November 21, 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: K230773
Trade/Device Name: Endoscopy Irrigation Tubing
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: October 25, 2023
Received: October 26, 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 (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, 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)*

K230773

Device Name
Endoscopy Irrigation Tubing

Indications for Use *(Describe)*

The 24 hour use Endoscopy Irrigation Tubing(tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via a sterile water bottle during gastrointestinal 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.**

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
# (K230773)

## 1. Submitter's information

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## 2. Date of Submission

9-March- 2023

## 3. Device

Trade/Device Name: Endoscopy Irrigation 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

## 4. Predicative device

510(k) Number: K202560
Device Name: AquaPulse® Irrigation Tubing
Product Code: OCX

## 5. Device description

The Endoscopy Irrigation Tubing is intended for 24-hour use and then discarded. The endoscopy irrigation tubing is manufactured for use in conjunction with sterile water bottle, and together with irrigation pumps. The endoscopy irrigation tubing is individually packed in sealed package, sold as a sterile device. The endoscopy irrigation tubing is designed to be attached to the auxiliary water connector or biopsy irrigation accessory and to be inserted into pump head of the irrigation pump to provide irrigation through the auxiliary water channel to the distal end of endoscope.

**6. Indications for use**

The 24 hour use Endoscopy Irrigation Tubing (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via a sterile water bottle during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

**7. Comparison of Technological Characteristics:**

| Item | Proposed device | Predicate device | Comparison to Predicate Devices |
|---|---|---|---|
| Device name | Endoscopy Irrigation Tubing | AquaPulse® Irrigation Tubing | / |
| Product code | OCX | OCX | Same |
| 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 24 hour use Endoscopy Irrigation Tubing(tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via a sterile water bottle during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump. | The 24 hour use AquaPulse® Irrigation Tubing (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via a sterile water bottle during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump. | Same |
| Compatibility | Model A is suitable for ENDOGATOR™ EGP-100 Irrigation Pump, OLYMPUS® OFP Pump, OLYMPUS® AFU-100 Pump and ERBE EIP2® Pump<br>Model B is suitable for Olympus® OFP, OFP-2, OFP-3 and OPF-3 Plus Irrigation Pump | Olympus® OFP, Endo Status™ EGA-500 and Endogator® EGP-100 Irrigation Pump | Substantial Equivalent |

| | | | |
|---|---|---|---|
| Materials | Polycarbonate (PC),Polyvinyl Chloride (PVC), Polypropylene (PP), Polytetrafluoroethylene(PTFE), Methyl Methacrylate Acrylonitrile Butadiene Styrene (MABS) and Silicone, Polyformaldehyde Resin(POM) | Polycarbonate and Polyvinyl Chloride | Similar, we have conducted the biocompatibility test and all tests have passed with acceptable results. |
| Environment of Use | Hospital and or clinics | Hospital and or clinics | Same |
| Single Use, Disposable | 24-hour use then discard | 24-hour use then discard | Same |
| Backflow Prevention Design | Diaphragm in the connector allow pressurized water passing through in one-way but not the other way | Diaphragm in the connector allow pressurized water passing through in one-way but not the other way | Substantial Equivalent |
| Supplied Sterile | Yes | Yes | Same |
| Packaging | Irrigation tubing is packaged in a sealed pouch | Irrigation tubing is packaged in a sealed pouch | Same |
| Manufacturing method | Injection molding and extrusion | Injection molding and extrusion | Same |
| Sterilization | EO gas | EO gas | Same |
| Shelf Life | Three years | One year | Substantial Equivalent |

**8. Performance Test**

The bench testing was performed on Endoscopy Irrigation Tubing to support substantial equivalence such as verification tests on flow performances of proposed devices and predicate devices. The performance data demonstrated that the proposed device met established specifications.

**9. Sterilization**

The proposed device are sold in a sterile package. The proposed device have been sterilized in a validated EO sterilization cycle. The EO residual was measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014-07-15“Sterilization of Health Care products Ethylene Oxide - Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices [Including: Amendment 1 (2018)]”, and ISO 10993-7 Second Edition 2008-10-15 “Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]”.

**10. Shelf Life**

The shelf-life of 3 years has been validated through accelerated aging 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 are also met. The test result can imply that the subject devices can provide and maintain a sterile barrier and its intended performance for at least the claimed shelf life.

**11. Biocompatibility**

The Biocompatibility testing was performed to show that all patient contacting materials meet applicable biocompatibility standards per ISO 10993-1:2018 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”. The cytotoxicity, sensitization and intracutaneous reactivity were performed to show that the proposed devices are biocompatible.

**12. Conclusions**

There are no significant differences between the proposed device and the predicate device, the proposed device doesn’t raise any new issues of safety and effectiveness. From a clinical perspective and comparing design specifications, the proposed device Endoscopy Irrigation Tubing is substantially equivalent to GA Health Company Limited currently marketed AquaPulse® Irrigation Tubing (K202560).