March 20, 2025

Hangzhou AGS MedTech Co., Ltd.
Yanping Fu
RA Manager
Building 2, 5 and 7, No. 389, Xingzhong Road
Linping District, Hangzhou, Zhejiang 311103
China

Re: K241704
Trade/Device Name: Endoscopic Water Pump
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OCX
Dated: February 17, 2025
Received: February 18, 2025

Dear Yanping Fu:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241704

Device Name

Endoscopic Water Pump

Indications for Use *(Describe)*

The Endoscopic Water Pump is a peristaltic pump intended to supply fluid to compatible endoscopes or endotherapy devices for irrigation of the gastric and colonic mucosa during endoscopic or endotherapeutic procedures, allowing to aid in visualisation, diagnosis and treatment.

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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CH2.03
510(k) Summary

510(k) Summary

We submit this 510(k) Summary as per 21 CFR 807.92, it meets the content and format regulatory requirements.

CH2.03.1 Submitter

Submitted by/Owner:	Hangzhou AGS MedTech Co., Ltd. Building 2, 5 and 7, No.389, Xingzhong Road, Linping District, 311103 Hangzhou, Zhejiang, PEOPLE'S REPUBLIC OF CHINA
Establishment Registration Number:	3010288205
Registration Status:	Active
Contact Person:	Yanping Fu Phone: 0086-15958493282 Fax: 0086- 0571-87671230 Email: fuyp@bioags.com
Date Prepared:	June 11, 2024

CH2.03.2 Proposed Device

Trade Name:	/
Device Name:	Endoscopic Water Pump
Common Name:	Endoscopic Water Pump
Regulation class:	Class II
Regulation Number:	876.1500
Regulation Description:	Endoscope and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	OCX
Product Code Name:	Endoscopic Irrigation/Suction System

CH2.03.3 Predicate Device

Trade Name:	/
Device Name:	Olympus Endoscopic Flushing Pump(OFP-2)
Common Name:	Endoscopic Flushing or Lavage Pump
510(K) Number:	K100899
Regulation class:	Class II
Regulation Number:	876.1500
Regulation Description:	Endoscope and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	FEQ
Product Code Name:	Pump, Air, Non-manual, For endoscope

CH2.03.4 Device Description

AGS's Endoscopic Water Pump comprises:

- A host machine (including drive system, peristaltic pump head, housing, etc.);
- Operating component (Rotatable Knob and Footswitch);
- Hanger assembly(optional);
- An irrigation tube (optional)

The Endoscopic Water Pump is a motorized pump designed to transfer water from a bottle, via a tube, to an endoscope or EndoTherapy devices, and the pump is operated by a footswitch. It uses a peristaltic pump head to move the water through the tube. The speed of the rotation of the pump head is adjustable by the user, using flow control knob on the front of the pump.

CH2.03.5 Indication for use statement

The Endoscopic Water Pump is a peristaltic pump intended to supply fluid to compatible endoscopes or endotherapy devices for irrigation of the gastric and colonic mucosa during endoscopic or endotherapeutic procedures, allowing to aid in visualization, diagnosis and treatment.

CH2.03.6 Comparison of Technology Characteristics

Our proposed device Endoscopic Water Pump is substantially equivalent to the predicate devices. The differences between Endoscopic Water Pump and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below:

Table CH2.03.6 Comparison of technical characteristics

Item		Proposed device Hangzhou AGS MedTech Co., Ltd.	Predicate device（K100899） OLYMPUS AMERICA INC	Comparison
Technical	**Configuration**	AGS's Endoscopic Water Pump comprises: - A host machine (including drive system, peristaltic pump head, housing, etc.); - Operating component (Rotatable Knob and Footswitch); - Hanger assembly(optional) - An irrigation tube (optional)	Olympus Flushing Pump comprises: - Flushing Pump OFP-2 host machine; - Power cord; - Footswitch; - Water container (optional); Water tube (optional);	Similar. AGS' Endoscopic Water Pump don't contain optional water container, while Olympus Flushing Pump contain optional water container, the difference don't raise question about safety and effectiveness.
Performance	Maximum output flow	Water feed: controlled by footswitch. Flow rate: variable, controlled from front panel. Flow rate delivery from the pump will depend on the length and type of endoscopes or EndoTherapy Accessory attached. The operator must therefore assess the condition of the patient and use clinical judgement to set the flow rate from the pump to avoid causing patient trauma. For endoscopes incorporating an auxiliary water channel and using irrigation tube AG-5247-3.2: The flow rate when using the GIF-HQ290 should be approx. 240~248ml/min when the pump head is new and its flow setting is 10 (maximum). The	Variable, controlled from front panel. **1.For endoscopes incorporating an auxiliary water channel and using auxiliary water channel tube MAJ-1608/MAJ-1651:** The flow rate when using the CF-Q180AL should be approx. 230ml/min when the pump head is new and its flow setting is 9 (maximum). The flow rate will reduce as the pump head deteriorates. We recommend flow settings of 1 - 6 for auxiliary water channel use. **2. For instrument channel flushing (1):** The flow rate when using the CF-Q260AL/DL (3.2mm diameter channel) without an instrument inserted should be approx. 785ml/min when the pump head is new and	Different. The difference doesn't raise question about safety and effectiveness. The detail analysis are as follow: 1) For endoscopes incorporating an auxiliary water channel, the maximum output flow of proposed device is big than predicate device, we confirmed that the proposed device can meet the clinical requirements through simulate the clinical use of proposed device. 2) For instrument channel flushing, the maximum output flow of

Item		Proposed device Hangzhou AGS MedTech Co., Ltd.	Predicate device（K100899） OLYMPUS AMERICA INC	Comparison
		flow rate will reduce as the pump head deteriorates. We recommend flow settings of 1-10 for auxiliary water channel use. For instrument channel flushing (1): The flow rate when using the GIF-Q260 (2.8mm diameter channel) without an instrument inserted should be approx. 240~258ml/min when the pump head is new and its flow setting is 10 (maximum). The flow rate will reduce as the pump head deteriorates. We recommend flow settings of 1 - 10 for instrument channel use.	its flow setting is 9 (maximum). The flow rate will reduce as the pump head deteriorates. We recommend flow settings of 5 - 9 for instrument channel use. **3. For instrument channel flushing (2):** The flow rate when using the GIF-Q260 (2.8mm diameter channel) with a 2.5mm diameter ultrasound probe inserted should be approx. 100ml/min when the pump head is new and its flow setting is 9 (maximum). The flow rate will reduce as the pump head deteriorates. We recommend flow settings of 5 - 9 for instrument channel use.	proposed device is big than predicate device, we confirmed that the proposed device can meet the clinical requirements through simulate the clinical use of proposed device. Above all, the simulation test in Section 12 which demonstrates the substantial equivalence of the Endoscopic Water Pump.
Shelf life		5 years for host machine	/	Different, the shelf life of predicate device is unknown, but we conducted the shelf life validation in Section 14 which can prove that the difference of shelf life doesn't raise different questions regarding its safety and effectiveness.
Irrigation tube	**Sterile Supplied**	Yes.	MAJ-1608, MAJ-1651 is single day use item, MAJ-1607, MAJ-1681, MAJ-1682 is single use,	Different. Our Irrigation tubes are sterile

Item		Proposed device Hangzhou AGS MedTech Co., Ltd.	Predicate device（K100899） OLYMPUS AMERICA INC	Comparison
			MAJ-1651, MAJ-1681 and MAJ-1682 supplied sterile	supplied, substantially equivalent.
	Shelf Life	3 years	unknown	Different. Shelf life of Predicate device is unknown, but we conducted the shelf life validation in Section 14 which can prove that the difference of shelf life doesn't raise different questions regarding its safety and effectiveness.
	Single Use	Yes	MAJ-1608, MAJ-1651 is single day use item	Different. Our Irrigation tubes are single use, substantially equivalent.
Biological	**Materials contacting with human body**	ABS, PVC, PC	unknown	Different The biological information of predicate device is unknown. And the biological risks are acceptable, please refer to Section 15.
	Biocompatibility	ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021	unknown	

CH2.03.7 Applicable Guidance Document

NA

CH2.03.8 Performance Data

The Endoscopic Water Pump meets all design specifications and medical device standards for electrical safety and EMC (IEC 60601), and the Irrigation tube meet the standard for sterility (ISO 11135). The non-clinical performance meets the design specification and shows substantial equivalence to the predicated device.

CH2.03.9 Clinical Test

No Clinical test is included in this submission.

CH2.03.10 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Hangzhou AGS MedTech Co., Ltd has demonstrated that proposed device Endoscopic Water Pump is substantially equivalent to the predicate devices.