June 24, 2026

Hangzhou AGS MedTech Co., Ltd.
Kai Zhang
Official Correspondent
Building 2, 5 and 7, No.389 Xingzhong Road
Linping District
Hangzhou, Zhejiang 311103
China

Re: K253393
Trade/Device Name: Single-use Balloon Dilatation Catheter
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE, KNQ
Dated: May 21, 2026
Received: May 21, 2026

Dear Kai Zhang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA
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)*

K253393

Device Name

Single-use Balloon Dilatation Catheter

Indications for Use *(Describe)*

The Single-use Balloon Dilatation Catheter is intended to endoscopically dilate strictures of the alimentary tract (involving biliary tract). The device is supplied sterile and intended for single use only.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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:	Kai Zhang Phone: +86-0571-87671223 Fax: +86-0571-87671230 Email: zhangkai@bioags.com
Date Prepared:	September 23, 2025

CH2.03.2 Proposed Device

Trade Name:	Single-use Balloon Dilatation Catheter
Device Name:	Single-use Balloon Dilatation Catheter
Common Name:	Single-use Balloon Dilatation Catheter
Regulation class:	Class II
Regulation Number:	876.5010
Regulation Description:	Biliary catheter and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	FGE, KNQ
Product Code Name:	FGE: Stents, drains and dilators for the biliary ducts KNQ: Dilator, esophageal FDS: Gastroscope and accessories, flexible/rigid FDF: Colonoscope and accessories, flexible/rigid

CH2.03.3 Predicate Device

Trade Name:	Reliant(TM) Multistage Dilatation Balloon Catheter
Device Name:	Reliant(TM) Multistage Dilatation Balloon Catheter
Common Name:	Reliant(TM) Multistage Dilatation Balloon Catheter
510(k) Number:	K180418
Regulation class:	Class II
Regulation Number:	876.5010
Regulation Description:	Biliary catheter and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	FGE, KNQ

Product Code Name:	FGE: Stents, drains and dilators for the biliary ducts KNQ: Dilator, esophageal

CH2.03.4 Device Description

The Single-use Balloon Dilatation Catheter is available in two types: standard and rapid exchange series. For the standard series, the Single-use Balloon Dilatation Catheter consists of a catheter assembly, double-lumen tube, balloon, tip, and two-way valve. For the rapid exchange series, it additionally includes a torque device, and there is a small hole on the catheter which is about 200mm far away from the distal end, it is used to insert the guide wire rapidly. The balloon can be inflated to three distinct sizes, 6-7-8mm, 8-9-10mm, 10-11-12mm, 12-13.5-15mm, 15-16.5-18mm, 18-19-20mm diameters; the balloon length can be 30mm, 55mm and 80mm. The effective length of the catheter is 1800mm, 1950mm, 2100mm and 2400mm with an outer diameter of 2.3mm. The device is provided sterile via Ethylene Oxide sterilization and is intended for single use only.

CH2.03.5 Indication for use statement

The Single-use Balloon Dilatation Catheter is intended to endoscopically dilate strictures of the alimentary tract (involving biliary tract). The device is supplied sterile and intended for single use only.

CH2.03.6 A description of the accessories

For Single-use Balloon Dilatation Catheter, no other devices and no other products that are not devices provided with it as accessories.

In clinical use:

1. The Single-use Balloon Dilatation Catheter must be used in conjunction with a flexible endoscope. The product is inserted through the flexible endoscope and advanced through its channel to the patient's lesion site, extending from the distal end of the endoscope channel.
2. The Single-use Balloon Dilatation Catheter must be used together with a guidewire. The guidewire is inserted through the guidewire lumen interface of the product and advanced until it extends from the distal end of the product.
3. The Single-use Balloon Dilatation Catheter must be used in combination with a balloon dilatation pressure pump. The injection port connector of this product complies with ISO 80369-7:2021 standards, enabling connection and fluid delivery with a compatible balloon dilatation pressure pump to inflate the balloon.

CH2.03.7 Comparison of Technology Characteristics

Our proposed device Single-use Balloon Dilatation Catheter is substantially equivalent to the predicate devices. The differences between the Single-use Balloon Dilatation Catheter and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below:

Table CH2.03.7 Comparison of technical characteristics

Item		Proposed device Hangzhou AGS MedTech Co., Ltd.	Predicate device （K180418） Micro-Tech (Nanjing) Co., Ltd	Comparion
Technical	Configuration	For the standard series, the Single-use Balloon Dilatation Catheter consists of Component, double-lumen tube, balloon, tip, and two-way valve. For the rapid exchange series, it additionally includes a torque device in Component, and there is a small hole on the catheter which is about 200mm far away from the distal end, it is used to insert the guide wire rapidly.	Tip, balloon, marker band, handle junction, and guidewire.	Similar. The predicate device includes an additional pre-loaded guidewire, while the subject device features an additional rapid exchange port. Apart from these differences, the main structures of the two products are identical.
	Effective length of catheter(mm)	1800，1950，2100，2400	1800，2300	Similar. The working length range of our product is 1800-2400mm, which is substantially consistent with the predicate device's range of 1800-2300mm.
Biological	Main Patient contact Material	Pebax	Pebax	Similar. Except for the pre-loaded guidewire, the proposed device and the predicate device share the same primary materials that contact the human body.

CH2.03.8 Performance Data

The Single-use Balloon Dilatation Catheter meets all design specifications and medical device standards for biocompatibility (ISO 10993) and sterility (ISO 11135). All necessary verification and validation tests have been performed on the proposed device to assure substantial equivalence to the predicate device. The tests include: Balloon appearance, Dimensional Verification, Leakage Testing, Peak Tensile Force, Radiopacity, Balloon Compliance (Diameter vs. Pressure), Balloon Rated Burst Pressure, Balloon Fatigue, Relief Time of Balloon, Guide Wire Compatibility, Endoscope Compatibility, and Simulated Use.

The non-clinical performance meets the design specification and shows substantial equivalence to the predicate device.

CH2.03.09 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 Single-use Balloon Dilatation Catheter is substantially equivalent to the predicate devices.