April 6, 2022

Hangzhou AGS MedTech Co., Ltd.
Jiayuan Zhang, RA Specialist
Building 5, Building 6, No.597 Kangxin Road Yuhang District
Hangzhou, Zhejiang 311106
CHINA

Re: K213578
Trade/Device Name: Balloon Dilatation Catheter
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FDF, KNQ, FDS
Dated: November 4, 2021
Received: November 10, 2021

Dear Jiayuan 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 (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, 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)*
K213578

Device Name
Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Balloon Dilatation Catheter is intended to endoscopically dilate strictures of the alimentary 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.

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510(k) Summary

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

5.1 Submitter

Submitter Information	Hangzhou AGS MedTech Co., Ltd. Building 5, Building 6, No.597 Kangxin Road Yuhang District, 311106 Hangzhou, Zhejiang, China
Establishment Registration Number:	3010288205
Registration Status:	Active
Contact Person:	Jiayuan Zhang Phone: 0086-18668235131 Fax: 0086-0571-87671225 Email: zhangjy@bioags.com
Date Prepared:	March 22, 2022

5.2 Proposed Device

Trade Name:	Not Applicable
Device Name:	Balloon Dilatation Catheter
Common Name:	Balloon Dilatation Catheter
Regulatory Class:	Class II
Regulation Number:	21 CFR § 876.1500
Regulation Name:	Endoscope and accessories,
FDA Review Panel:	Gastroenterology/Urology
Product Code(s):	FDF, KNQ, FDS
Product Code Name:	FDF: Colonoscope And Accessories, FDS: Gastroscope And Accessories, KNQ: Dilator, Esophageal

5.3 Predicate Device

Trade Name:	CRE™ Balloon Dilation Catheter
Common Name:	Dilation catheter
510(k) Number:	K110833
Regulatory Class:	Class II
Regulation Number:	21 CFR § 876.1500
Regulation Description:	Endoscope and accessories
FDA Review Panel:	Gastroenterology/Urology
Product Code(s):	FDT, FDF, KNQ
Product Code Name:	FDT: Duodenoscope And Accessories, Flexible/Rigid FDF: Colonoscope And Accessories, Flexible/Rigid KNQ: Dilator, Esophageal

5.4 Device Description

The proposed device Balloon Dilatation Catheter is comprised of a pebax balloon mounted at the distal end of a pebax catheter with two ports. 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. Radiopaque bands placed at the distal and proximal end of the device provide fluoroscopic visualization of the balloon location. The catheter length is 1800mm, 1950mm, 2100mm and 2400mm with an outer diameter of 1.8mm, 2.0mm or 2.3mm. The two ports correspond to a guide wire port and balloon inflation port. A stopcockis included at the proximal end of the balloon inflation port to control pressure movement into or out of the device. For rapid exchange models, 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 Dilatation Catheter is EO sterilization and use for single use only.

5.5 Indication for Use statement

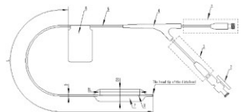
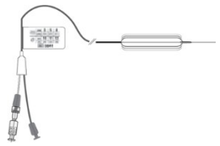
The Balloon Dilatation Catheter is intended to endoscopically dilate strictures of the alimentary tract. The device is supplied sterile and intended for single use only.

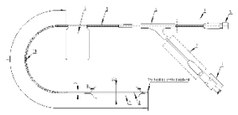
5.6 Comparison of Technology Characteristics

Our proposed device Balloon Dilatation Catheter is substantially equivalent to the predicate devices. The differences between the 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 5.6 Comparison of technical characteristics

Item		Proposed device	Predicate device	Comparison
Trade name		Not applicable	CRE^{TM} Wireguided Balloon Dilatation Catheter	/
Model number		5251 series, 5252 series	M00558500*****, M00558450, M00558460, M00558470, M00558480, M00558490 M00558390, M00558400, M00558410, M00558420, M00558430, M00558440****	/
510(k) submitter		Hangzhou AGS MedTech Co., Ltd.	Boston Scientific Corporation	/
510(k) number		K213578	K110833	/
Clinical	Intended use	The Balloon Dilatation Catheter is intended to endoscopically dilate strictures of the alimentary tract. The device is supplied sterile and intended for single use only.	Indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. The recommended application is printed on the package label referring to any combination of esophageal, pyloric and colonic dilatation.	Similar. Our proposed device has the smaller applicable population range.
	Applicable population	Adults	Adult and adolescent populations	Different. Our proposed device has the smaller applicable population range.

Technical	Principles of operation	Balloon Dilatation Catheter is a device that operated on the principle of inflating a balloon attached to the distal end of catheter, to dilate strictures of the alimentary tract. Radiopaque bands placed at the distal and proximal ends of the balloon provide fluoroscopic visualization of the balloon location. The Balloon Dilatation Catheter is capable of 3 distinct and progressively larger size diameters via controlled radial expansion. Specific balloon sizes are printed on each package and small label.	The CRE Wireguided Balloon Dilatation Catheter is capable of 3 distinct and progressively larger size diameters via controlled radial expansion. Specific balloon sizes are printed on each package and hub label.	Similar.
	Rapid exchange or not	For 5251 Series : No For 5252 series: Yes	No	Different. We use K172520 as reference device to support this technological characteristic.
	Device picture and structure	Drawing of Balloon Dilatation Catheter (for 5251 series)  1.Guide wire port 2.On-off valve 3.Balloon inflation 4.Base port 5.Catheter 6.Small label 7.Balloon 8.Radiopaque band		Similar

		Drawing of Balloon Dilatation Catheter (for 5252 series)  1 Guide wire port 2.On-off valve 3.Balloon inflation 4.Base port 5.Catheter 6.Small label 7.Balloon 8.Radiopaque band 9.Luer cap 10.RX support wire		
	Outer diameter	1.8mm, 2.0mm, 2.3mm	2.5mm (7.5Fr)	Similar.
	Balloon length	30mm, 55mm, 80mm;	55mm	Similar. Our proposed device has more specifications to be chosen.
	Working length	1800mm, 1950mm, 2100mm, 2400mm	2400mm, 1800mm	Similar. Our proposed device has more specifications to be chosen.
	Suitable working channel of endoscope	For 5252 series: 3.7 mm	2.8 mm	Different. We use K172520, K112994 and K122924 as reference devices to support this technological characteristic.
Biological	Materials or substances in contact with the same human tissue or body fluids	PEBAX	No exact information.	Different. Biocompatibility tests have been done for the difference. Biological risks are acceptable.
	Biocompatibility	In Vitro Cytotoxicity Test: ISO 10993-5: 2009; Skin sensitization Test: ISO	No exact information.	

		10993-10: 2010; Intracutaneous Reactivity Test: ISO 10993-10: 2010; Acute Systemic Toxicity Test: ISO 10993-11:2017; Pyrogenicity: ISO 10993-11:2017;		

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The Balloon Dilatation Catheter meets all design specifications and medical device standards for biocompatibility (ISO 10993) and sterility (ISO 11135). The non-clinical performance meets the design specification and shows substantial equivalence to the predicated device.

Following tests were conducted in our non-clinical bench test:

- The head tip of the distal end;
- Connect strength;
- Leakage performance;
- Balloon fatigue performance;
- Balloon position detectability;
- Interface compatibility with endoscope;
- Compatibility with guide wire;
- Compatibility with luer taper.

5.9 Clinical Test

No Clinical test is included in this submission.

5.10 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 Balloon Dilatation Catheter is substantially equivalent to the predicate devices.