May 1, 2020

Hangzhou AGS MedTech Co., Ltd.
Chunqi Han
R&D Director
Building 5, Building 6, No.597
Kangxin Road Yuhang District
Hangzhou, 311106
CHINA

Re: K200173
Trade/Device Name: Stone Retrieval Balloon
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: GCA
Dated: January 21, 2020
Received: January 23, 2020

Dear Chunqi Han:

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,

Daniel G. Walter, Jr.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200173

Device Name
Stone Retrieval Balloon

Indications for Use *(Describe)*
The device is intended for endoscopic removal of biliary stones. 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

Submitted by/Owner:	Hangzhou AGS MedTech Co., Ltd. Building 5, Building 6, NO.597 Kangxin Road Yuhang District, Hangzhou, Zhejiang 311106 China
Establishment Registration Number:	3010288205
Registration Status:	Active
Contact Person:	Yanping Fu Phone: 0086-15958493282 Fax: 0086- 0571-87671225 Email: fuyp@bioags.com
Date Prepared:	July 18, 2019

5.2 Proposed Device

Trade Name:	/
Device Name:	Stone Retrieval Balloon
Common Name:	Stone Retrieval Balloon
Regulation class:	Class II
Regulation Number:	876.5010
Regulation Description:	Biliary Catheter and Accessoriess
Review Panel:	Gastroenterology/Urology
Product Code:	GCA
Product Code Name:	Biliary Catheter For Stone Removal That May Also Allow For Irrigation And Contrast Injection

5.3 Predicate Device

Trade Name:	Tri-Ex Extraction Balloon With Multiple Sizing
Device Name:	Tri-Ex Extraction Balloon With Multiple Sizing
Common Name:	Extraction Balloon With Multiple Sizing
510(k) Number:	K170292
Regulation class:	Class II
Regulation Number:	876.5010
Regulation Description:	Biliary Catheter and Accessoriess
Review Panel:	Gastroenterology/Urology
Product Code:	GCA
Product Code Name:	Biliary Catheter For Stone Removal That May Also Allow For Irrigation And Contrast Injection

Trade Name:	Single Use 3-Lumen Extraction Balloon V
Device Name:	Single Use 3-Lumen Extraction Balloon V
Common Name:	3-Lumen Extraction Balloon
510(k) Number:	K091495
Regulation class:	Class II
Regulation Number:	876.5010
Regulation Description:	Biliary Catheter and Accessoriess
Review Panel:	Gastroenterology/Urology
Product Code:	FGE/LQR
Product Code Name:	Stents, Drains And Dilators For The Biliary Ducts/ Dislodger, Stone, Biliary

5.4 Device Description

The subject Stone Retrieval Balloon is comprised of a latex balloon mounted at the distal end of a Pebax catheter with three internal lumens. For some models, the balloon can be inflated to 8.5mm, 12mm, 15mm and 18mm only. But for some models, the balloon can be inflated to three sizes, 8.5 mm, 12 mm and 15 mm diameters, or 13mm, 15mm and 18mm. Radiopaque bands placed at the distal and proximal ends of the balloon provide fluoroscopic visualization of the balloon location. The catheter length is 2000mm with a outer diameter of 2.4mm. The three lumens correspond to a balloon inflation port, a wire guide port and an injection port. A stopcock is included at the proximal end of the balloon inflation port to control air movement into or out of the balloon. 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. EO Sterilization and use for single use only.

5.5 Indication for use statement

The device is intended for endoscopic removal of biliary stones. The device is supplied sterile and intended for single use only.

5.6 Comparison of Technology Characteristics

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

Difference Item		Proposed device	Predicate device	Comparison
Common name		Stone Retrieval Balloon	Tri-Ex Extraction Balloon with Multiple Sizing	/
Trade name		/	Tri-Ex Extraction Balloon with Multiple Sizing	/
Model number		5051 series, 5053 series, 5451series, 5453 series	TXR-8.5-12-15-A	/
510(k) submitter		Hangzhou AGS MedTech Co., Ltd.	Wilson-Cook Medical, Inc.	/
510(k) number		/	K170292	/
Technical	Balloon Max outer diameter	8.5/12/15/18/8.5-12-15/13-15-18mm	8.5 mm, 12 mm and 15mm	Different. Our balloon outer diameter includes a range from 8.5mm to 18mm, the predicate device includes a range from 8.5mm to 15mm. For the 18mm balloon, we provide the following support evidence to demonstrate that it will not raise different questions regarding its safety and effectiveness. First, we searched in the FDA 510k Premarket Notification database for other similar retrieval balloon catheter, and we found Olympus's 3-Lumen Extraction Balloon (K091495), maximum diameter of the balloon(mm) is 20mm, it is shown in the 510(k) summary: Second, there is a literature that retrieval balloon catheter is used to remove stones in the bile duct which the mean common bile duct (CBD) dilation was 19.2mm±3.9 and the mean size of stones 15.8±2.9.

Difference Item		Proposed device	Predicate device	Comparison
	Recommended Wire Guide Diameter inch	0.035 /0.025ich	0.035ich	Different. Our proposed device has another option for wire guide, the difference don't raise question about safety and effectiveness.
	Performance	Balloon Diamater, Balloon Deflation, Balloon Strength, etc.	Balloon Diameter, Balloon Deflation, Balloon Strength, etc.	Different. We conduct bench performance for our proposed device and the predicate device, please refer to Section 18 of this submission, the test results show that our proposed device is substantial equivalence with the predicate device.
Biological	Materials or substances in contact with the same human tissue or body fluids	Sheath: Pebax; Radiopaque band: Tal; Bind wire: PET; Laxtex balloon: Natural latex; Binder: UV-curing adhensive; Marker: Polyurethane ink.	Catheter: nylon; Balloon: Latex.	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 10993-10: 2010; Intracutaneous Reactivity Test: ISO 10993-10: 2010;	Unknown	

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The Stone Retrieval Balloon 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.

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 Electrosurgical System is substantially equivalent to the predicate devices.