March 3, 2023

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

Re: K221713
Trade/Device Name: Polypectomy Snare
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: FDI
Dated: January 30, 2023
Received: January 31, 2023

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,

Sivakami Venkatachalam -S

for
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)*
K221713

Device Name
Polypectomy Snare

Indications for Use *(Describe)*
Polypectomy Snare is used endoscopically in the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

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

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, 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 3, 2023

5.2 Proposed Device

Trade Name:	Polypectomy Snare
Device Name:	Polypectomy Snare
Common Name:	Polypectomy Snare
Regulation class:	Class II
Regulation Number:	876.4300
Regulation Description:	Endoscopic electrosurgical unit and accessories.
Review Panel:	Gastroenterology/Urology
Product Code:	FDI
Product Code Name:	Snare, Flexible

5.3 Predicate Device

Trade Name:	Polypectomy Snare
Device Name:	Polypectomy Snare
Common Name:	Polypectomy Snare
510(k) Number:	K172729
Regulation class:	Class II
Regulation Number:	876.4300
Regulation Description:	Endoscopic electrosurgical unit and accessories.
Review Panel:	Gastroenterology/Urology
Product Code:	FDI
Product Code Name:	Snare, Flexible

5.4 Device Description

Polypectomy Snare described in this submission is a sterile, single use devices compatible with the working channel of endoscope. The device is used endoscopically in the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract. The device can remove the specified released Hemoclip. EO sterilization and use for single use only.

5.5 Indication for use statement

Polypectomy Snare is used endoscopically in the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

5.6 Comparison of Technology Characteristics

Our proposed device Polypectomy Snare is substantially equivalent to the predicate device. The differences between the Polypectomy Snare and the predicate device 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 (K172729)	Comparison
Common name		Polypectomy Snare	Polypectomy Snare	/
Trade name		/	/	/
Model number		5071, 5072, 5073, 5074, 5075, 5076, 5077, 5078, 5079, 50710 series	5071, 5072, 5073, 5074, 5075, 5076, 5077, 5078, 5079, 50710 series	/
510(k) submitter		Hangzhou AGS MedTech Co., Ltd.	Hangzhou AGS MedTech Co., Ltd.	/
510(k) number		/	K172729	/
Technical	Principles of operation	The polypectomy snare is intended to pass through the endoscope via working channel. When the electrode appears in the endoscopic view, push the sliding handle forward to extend the electrode from the sheath tube. The electrode can be extended to a certain open width in order to trap the target tissue. Pull the sliding handle back to hold the target tissue within the electrode loop. For hot indication, activate the electrode. The snare electrode delivers a high frequency current to cut and cauterize tissue, and then achieves separation and coagulation of the tissue. For cold indication, pull the sliding handle back and without activating the electrode. Continually pull the sliding handle and cut the tissue mechanically with the electrode. For remove indication, the device can remove the specified released Hemoclip (manufactured by Hangzhou AGS, K211787). There	The polypectomy snare consists of handle, sheath, flexible wire and electrode, which is used endoscopically in the removal of diminutive and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract. When passed through an endoscope and activated, the snare delivers a monopolar electrical current to cut and cauterize tissue with the electrode.	Similar. For proposed device, add the cold indication and the remove indication. Bench test has been conducted to demonstrate substantial equivalence, please refer to Section 18 bench performance testing.

Item		Proposed device	Predicate device (K172729)	Comparison
		is a locking hook at the end of the Hemoclip's clips, when the clip part released after the closing movement, the locking hook forms a buckle with the groove at the lower end of the frap tube, making the two clips self-locking and closing, so as to achieve mechanical suture of the tissue at the lesion. Intraoperative, when operators find close position is not ideal, need to be adjusted to remove the released and closed clip head, they could take a snare product, since the endoscopic clamp inserts, in the perspective of endoscopic, the snare loop goes into the grooves, gradually tightening the snare loop, apply a pressure to the locked hook, press the hooks in, release the lock buckle, so that the two closed clips open, and the closed clip head leave the original lesion site; The snare loop tightens the opened clip head and exits from the human digestive tract together with the endoscope. Then the endoscope was reintroduced into the human digestive tract and the operation continued.		
	Snare open width	10mm, 15mm, 25mm, 32mm	10mm, 15mm, 25mm, 32mm	Substantial equivalence. We conducted bench test on our proposed device in comparison with our chosen predicate. All the test results show that the proposed device is as safe and effective as our predicate device. For bench tests reports, please refer to Section

Item		Proposed device	Predicate device (K172729)	Comparison
				18 of this submission.
	Electrode shape	Oval, shield, diamond, hexagon, polygon, round, crescent	Oval, hexagon, polygon, round, duck bill	Different. Bench test has been conducted to demonstrate substantial equivalence, please refer to Section 18 bench performance testing.
	Loop length	16mm, 22mm, 30mm, 31mm, 45mm, 50mm, 52mm, 60mm;	28mm, 32mm, 50mm, 63mm	Different. Bench test has been conducted to demonstrate substantial equivalence, please refer to Section 18 bench performance testing.
	Loop area	130mm^2, 135mm^2, 140mm^2, 210mm^2, 245mm^2, 250mm^2, 400mm^2, 650mm^2, 790mm^2, 830mm^2, 1050mm^2, 1250mm^2	225mm^2, 330mm^2, 850mm^2, 1335mm^2	Different. Bench test has been conducted to demonstrate substantial equivalence, please refer to Section 18 bench performance testing.
	Usability performance	1. Durability of mechanical resection; 2. Extension and retraction of snare loop; 3. Rotation degree of snare loop; 4. Tilting length; 5. Change of loop width; 6. Durability of snare loop wire-Pull force of keeping required width; 7. Durability of snare loop wire-Service life of snare loop; 8. Disassembly performance; 9. Mechanical cutting force.	1. Durability of mechanical resection; 2. Extension and retraction of snare loop; 3. Rotation degree of snare loop; 4. Tilting length; 5. Change of loop width; 6. Durability of snare loop wire-Pull force of keeping required width; 7. Durability of snare loop wire-Service life of snare loop;	Substantial equivalence. We conducted usability performance test on our proposed device in comparison with our chosen predicate. All the test results show that the proposed device is as safe and effective as our predicate device. For bench tests reports, please refer to Section 18 of this submission.
Electrical safety		The electrical safety performance of the polypectomy snare should meet the requirements of IEC 60601-1: 2005+A1:2012, IEC 60601-2-2:2017 and IEC	The electrical safety performance of the polypectomy snare should meet the requirements of IEC 60601-1: 2005+A1:2012, IEC	Similar. We conducted Electrical safety on our proposed device, for test reports, please refer to Section

Item	Proposed device	Predicate device (K172729)	Comparison
	60601-2-18.	60601-2-2:2009 and IEC 60601-2-18.	17 of this submission.

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The Polypectomy Snare meets all design specifications and medical device standards for electrosurgical safety (IEC 60601), 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:

Durability of mechanical resection;

Extension and retraction of snare loop;

Rotation degree of snare loop;

Tilting length;

Change of loop width;

Durability of snare loop wire-Pull force of keeping required width;

Durability of snare loop wire-Service life of snare loop;

Disassembly performance;

Mechanical cutting force.

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 Polypectomy Snare is substantially equivalent to the predicate device.