May 21, 2018

Hangzhou AGS MedTech CO., Ltd
% Ethan Liu
RA Specialist
Shanghai Thinkwell Consulting Co., Ltd.
Xin Ling Road, 211/6F
Shanghai, 201100
China

Re: K172729
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: April 13, 2018
Received: April 20, 2018

Dear Ethan Liu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172729

Device Name
Polypectomy Snare

Indications for Use *(Describe)*

Polypectomy Snare is used endoscopically in the removal of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI 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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1 Submitter

Submitted by:	Hangzhou AGS MedTech CO., Ltd. Building 6, Kangxin Road No.597, Qianjiang Economic Development Area , Hangzhou , Zhejiang , 311106, China
Establishment Registration Number:	3010288205
Owner/Operator Number:	10052959
Contact Person:	Ethan Liu Phone:0086-15216699240 Fax: 0086-21-60732022 Email:xtdeepwater@126.com
Date Prepared:	Jan 18, 2017

5.2 Device

Device Name:	Polypectomy Snare
Common Name:	Polypectomy Snare
Regulatory Class:	Class II
Regulation Number	876.4300
Product Code Name:	Snare, Flexible
Regulation Name：	Endoscopic electrosurgical unit and accessories
Product Code:	FDI

5.3 Predicate Device

Device Name:	Single Use Polypectomy Snares Captivator II, Single-Use Polypectomy Snares K133987
Common Name:	Polypectomy Snare
Regulatory Class:	Class II
Regulation Number	876.4300
Product Code Name:	Snare, Flexible
Regulation Name：	Endoscopic electrosurgical unit and accessories
Product Code:	FDI

5.4 Device Description

The polypectomy snare consists of handle, sheath, flexible wire and electrode that is used to remove polys utilizing monopolar RF energy under endoscopic visualization.

The rotary snares' cable and polypectomy can be rotated using the rotation actuator on the handle.

Polypectomy snare is sterile for single use with no delayed hypersensitivity and no intracutaneous reactivity, have no animal or human origin substance.

The electrode of polypectomy snare has five shapes to be used in clinical practice: Oval, Polygon, Duck Bill, Hexagonal and Round, and the electrode can extend, retract from the snare's flexible outer sheath.

5.5 Indication for Use:

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

5.6 Technology Characteristics

The polypectomy snare consists of handle, sheath, flexible wire and electrode, which are used endoscopically in the removal 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.

The proposed device contain both rotary and non-rotary specifications, the rotary snares' cable and polypectomy can be rotated using the rotation actuator on the handle, the main differences of these specifications are dimension.

5.7 Applicable Guidance Document

Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology

5.8 Substantial Equivalence

Captivator II, Single-Use Polypectomy Snare(Boston Scientific Corporation, K133987) is used as predicate device compared to proposed device Polypectomy Snare manufactured by Hangzhou MedTech Co., Ltd.

5.9 Performance Data

5.9.1 Biocompatibility Testing

The biocompatibility evaluation for this device was conducted in accordance with the FDA Bluebook Memorandum G95-1 "Use Of International Standard ISO-10993, 'Biological Evaluation Of Medical Devices Part 1: Evaluation And Testing.'" and the International Standard ISO 10993-1 Fourth Edition 2009-10-15, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)], as recognized by FDA.

Biocompatibility Test	Standards	Test Result	Verdict

In Vitro Cytotoxicity	ISO 10993-5:2009	No cytotoxicity observed.	Pass
Delayed-type Hypersensitivity	ISO 10993-10:2010	No hypersensitivity observed	Pass
Irritation	ISO 10993-10:2010	No irritation observed	Pass

5.8.2 Performance Testing

The following bench tests were performed on Polypectomy snare: Appearance, Size, Material, Usability, Electric property. The results of all testing were passing.

5.9 Clinical Test Conclusion

No Clinical Study is included in this submission.

5.11 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 Boston Scientific Corporation's currently marketed Captivator II, Single-Use Polypectomy Snares(K133987).