May 21, 2020

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

Re: K192342
Trade/Device Name: Electrosurgical System
(Electrosurgical Generator with Bipolar polypectomy snare combination and Single use electrosurgical knife combination accessories)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KNS
Dated: August 23, 2019
Received: August 28, 2019

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,

for
Shani 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192342

Device Name

Electrosurgical System (Electrosurgical Generator with Bipolar polypectomy snare combination and Single use electrosurgical knife combination accessories)

Indications for Use *(Describe)*

Electrosurgical Generator is intended to deliver High Frequency (HF) electrical current for the cutting and/or coagulation of tissue.

Bipolar Polypectomy Snare Combination has been designed to be used with endoscope and electrosurgical unit for the removal of sessile polyps, pedunculated polyps, tissue and foreign bodies from within the GI tract using high-frequency current.

Single Use Electrosurgical Knife Combination has been designed to be used with endoscopes and electrosurgical units to cut tissue within the digestive tract using high-frequency current.

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.

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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:	Electrosurgical System (Electrosurgical Generator with Bipolar polypectomy snare combination and Single use electrosurgical knife combination accessories)
Device Name:	Electrosurgical System (Electrosurgical Generator with Bipolar polypectomy snare combination and Single use electrosurgical knife combination accessories)
Common Name:	Electrosurgical System
Regulation class:	Class II
Regulation Number:	876.4300
Regulation Description:	Endoscopic electrosurgical unit and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	KNS
Product Code Name:	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)

5.3 Predicate Device

Trade Name:	ERBE ESU Model VIO 300D with Accessories
Device Name:	ERBE ESU Model VIO 300D with Accessories
Common Name:	Electrosurgical Unit (ESU/Generator) System
510(k) Number:	K083452
Regulation class:	Class II
Regulation Number:	21 CFR 878.4400
Regulation Description:	Electrosurgical cutting and coagulation device and accessories.

Review Panel:	General & Plastic Surgery
Product Code:	GEI
Product Code Name:	Electrosurgical, Cutting & Coagulation & Accessories

Trade Name:	Polypectomy snare
Device Name:	Polypectomy snare
Common Name:	Polypectomy snare
510(k) Number:	K172729
Regulation class:	Class II
Regulation Number:	21 CFR 876.4300
Regulation Description:	Endoscopic electrosurgical unit and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	FDI
Product Code Name:	Snare, Flexible

Trade Name:	Single use Electrosurgical Knife Series
Device Name:	Single use Electrosurgical Knife Series
Common Name:	Electrosurgical Knife
510(k) Number:	K092309
Regulation class:	Class II
Regulation Number:	21 CFR 876.4300
Regulation Description:	Endoscopic electrosurgical unit and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	KNS
Product Code Name:	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)

Trade Name:	Single use Electrosurgical knife
Device Name:	Single use Electrosurgical knife
Common Name:	Single use Electrosurgical knife
510(k) Number:	K171158
Regulation class:	Class II
Regulation Number:	21 CFR 876.4300
Regulation Description:	Endoscopic electrosurgical unit and accessories
Review Panel:	Gastroenterology/Urology
Product Code:	KNS
Product Code Name:	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)

5.4 Device Description

The Electrosurgical System comprises:

- Electrosurgical Generator;
- Bipolar polypectomy snare combination;

- Single use electrosurgical knife combination.

The Electrosurgical Generator is designed to deliver bipolar high-frequency current for the purpose of cutting and coagulating tissue. It consists of High frequency generator, footswitch, bipolar connecting cable and power cord. The Electrosurgical Generator output is actuated via a two-pedal Footswitch. One pedal activated the bipolar high-frequency current output for cut; the other pedal activates the bipolar high-frequency current output for coagulation. The Electrosurgical Generator incorporates proprietary software developed by AGS for generating and controlling the two energies delivered. The Bipolar connecting cable connects electrosurgical instruments to the Electrosurgical Generator, it transfer electrical energy - without changing the energy – from devices to instruments. The Electrosurgical Generator, Footswitch, Bipolar connecting cable and Power cord are non-sterile and reusable.

Bipolar polypectomy snare combination is an accessory to Electrosurgical Generator. It is a sterile device consists of Polypectomy snare (Bipolar) and Distal attachment. It is for endoscopic use. It is used for removal of polyps within the digestive tract using high-frequency current. EO sterilization and use for single use only.

Single use electrosurgical knife combination is an accessory to Electrosurgical Generator. It is a sterile device consists of Single use electrosurgical knife and Distal attachment. It is for endoscopic use. It is used for cutting tissues within the digestive tract using high-frequency current. EO sterilization and use for single use only.

5.5 Indication for use statement

Electrosurgical Generator is intended to deliver High Frequency (HF)
electrical current for the cutting and/or coagulation of tissue.

Bipolar Polypectomy Snare Combination has been designed to be used with endoscope and electrosurgical unit for the removal of sessile polyps, pedunculated polyps, tissue and foreign bodies from within the GI tract using high-frequency current.

Single Use Electrosurgical Knife Combination has been designed to be used with endoscopes and electrosurgical units to cut tissue within the digestive tract using high-frequency current.

5.6 Comparison of Technology Characteristics

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

5.6.1 Electrosurgical Generator

Difference	Proposed device	Predicate device K083452	Performance Testing
Output parameters	CUT I: Rated Output frequency: 460 kHz±10%; Max. voltage output: 480Vp;	Bipolar CUT: Rated Output frequency: 350kHz ±10%; Max. voltage output: 740Vp;	Different rated output frequency, but in the range of 200k-500MHz; Electrical safety reports. Thermal Effect on Tissue study report; The difference raises no new questions regarding safety and efficacy.
	CUT II: Working mode: Bipolar; Rated Output frequency: 460 kHz±10%; Rated Power: 120W±20%; Max. voltage output: 650Vp; Crest factor: 1.4~6.3	ENDO CUT Q: Working mode: Monopolar; Rated Output frequency: 350kHz ±10%; Rated Power: 400W+0%/-20%; Max. voltage output: 770Vp; Crest factor: 1.4（R_L=500Ω）	Electrical safety reports. Thermal Effect on Tissue study report; Animal study report; The difference raises no new questions regarding safety and efficacy.
	CUT III: Working mode: Bipolar; Rated Output frequency: 460kHz±10%; Rated Power: 60W±20%; Max. voltage output: 560Vp; Crest factor: 1.9~7.6	ENDO CUT I: Working mode: Monopolar; Rated Output frequency: 350kHz ±10%; Rated Power: 170W±20%; Max. voltage output: 550Vp; Crest factor: 1.4（R_L=500Ω）	Electrical safety reports. Thermal Effect on Tissue study report; Animal study report; The difference raises no new questions regarding safety and efficacy.
	COAG I: Rated Output frequency: 460 kHz±10%; Rated load: 100Ω;	Bipolar Soft COAG: Rated Output frequency: 350kHz ±10%; Rated load: 75Ω;	Different rated output frequency, but in the range of 200k-500MHz; Electrical safety reports. Thermal Effect on Tissue study report;

Difference	Proposed device	Predicate device K083452	Performance Testing
			The difference raises no new questions regarding safety and efficacy.
	COAG II: Rated Output frequency: 460 kHz±10%;	Bipolar Forced COAG: Rated Output frequency: 350kHz±10%;	Different rated output frequency, but in the range of 200k-500MHz; Electrical safety reports. Thermal Effect on Tissue study report; The difference raises no new questions regarding safety and efficacy.

5.6.2 For Bipolar polypectomy snare combination

Difference	Proposed device	Predicate device K172729	Performance Testing
Principles of operation	Bipolar Polypectomy Snare Combination is an applied part of electrosurgical generator, using bipolar high-frequency current delivered by the electrosurgical generator to cut and coagulate tissue with the electrode. We designed a diffusion electrode attached to the tip of its sheath and an active electrode attached to the electrode on the end of the sheath, and designed the Distal Attachment to connect with the diffusion electrode to provide a larger contact area. The high-frequency electricity flows from the electrode to the Distal Attachment. Distal Attachment provides a return path for high-frequency current with a low	Monopolar Polypectomy Snare manufactured is an applied part of electrosurgical generator, using monopolar high-frequency current delivered by the electrosurgical generator to cut and coagulate tissue with the electrode. The high-frequency electricity flows from the active electrode to the neutral electrode placed on patient skin.	Electrical safety reports. Thermal effect on tissue study report. The difference raises no new questions regarding safety and efficacy.

Difference	Proposed device	Predicate device K172729	Performance Testing
	current density and closer to the other electrode, to reduce the area of human tissue where high-frequency currents circulate and prevent the occurrence of anticipated burns in human tissue. No neutral electrode is needed.		
Energy Use	Biopolar High-Frequency Current	Monopolar Radio Frequency Current	Electrical safety reports. Thermal effect on tissue study report. The difference raises no new questions regarding safety and efficacy.
Structure	Bipolar Polypectomy snare combination consists of Polypectomy snare (Bipolar) and Distal Attachment. Polypectomy snare (Bipolar) consists of Electrode, External tube, Sheath tube, Base, Connector, Handle and Conductor. Distal Attachment consists of Plastic cap, Connect piece, Metal tube and Connect tube.	Polypectomy snare consists of Electrode, Sheath, Fixed/Rotary part, Sliding handle, Connector plug and handle.	Bench testing report. Thermal effect on tissue study report. The difference raises no new questions regarding safety and efficacy.
Materials or substances in contact with the same human tissue or body fluids	1. Polypectomy Snare (Bipolar): Sheath: PTFE; External tube:SUS304; Electrode:SUS304; 2.Distal Attachment: Plastic Cap: TPE; Connect piece: SUS304;	Sheath: PTFE; Electrode: SUS304;	Biocompatibility tests reports. The difference raises no new questions regarding safety and efficacy.

Difference	Proposed device	Predicate device K172729	Performance Testing
	Metal tube: SUS303; Connect tube:SUS304;		

5.6.3 For Single use electrosurgical knife combination

Difference	Proposed device	Predicate device K171158; K092309;	Performance Testing
Principles of operation	AGS's Bipolar Electrosurgical Knife Combination is an applied part of electrosurgical generator, using bipolar high-frequency current delivered by the electrosurgical generator to cut and cauterize tissue with the electrode. The Bipolar Electrosurgical Knife Combination has a diffusion electrode (named 'External tube') attached to the tip of its sheath and an active electrode attached to the knife on the end of the sheath. The active electrode is used to perform cut and cauterize while the external tube provides a return path for bipolar high-frequency current. However, the contact area of External tube is so small, we design the Distal Attachment to provide a larger contact area. Distal Attachment is installed at the distal end of the endoscope, Bipolar Single Use Electrosurgical Knife pass through the channel of endoscope, connect tube of the Distal Attachment	Monopolar Single Use Electrosurgical Knife is an applied part of electrosurgical generator, using monopolar high-frequency current delivered by the electrosurgical generator to cut and cauterize tissue with the electrode. The high-frequency electricity flows from the active electrode to the neutral electrode placed on patient skin.	Electrical safety reports. Thermal effect on tissue study report. The difference raises no new questions regarding safety and efficacy.

Difference	Proposed device	Predicate device K171158; K092309;	Performance Testing
	connect with the External tube of the Bipolar Single Use Electrosurgical Knife. The high-frequency electricity flows from the knife to the Distal Attachment. Distal Attachment provides a return path for high-frequency current with a low current density and closer to the other electrode, to reduce the area of human tissue where high-frequency currents circulate and prevent the occurrence of anticipated burns in human tissue.		
Energy Use	Biopolar High-Frequency Current	Monopolar Radio Frequency Current	Electric safety reports. Thermal effect on tissue study report. The difference raises no new questions regarding safety and efficacy.
Structure	Single use electrosurgical knife combination consists of single use electrosurgical knife and distal attachment. Single use electrosurgical knife consists of electrode part, sheath part and handle part. Distal Attachment consists of Plastic cap, Connect piece, Metal tube and Connect tube.	Single use electrosurgical knife consists of electrode part, sheath part and handle part.	Bench test report. Thermal effect on tissue study report. The difference raises no new questions regarding safety and efficacy.
Maximum insertion portion diameter	Φ2.4mm	KD-655 L: Φ2.7mm; KD-620LR: Φ2.6mm;	Bench test report. The difference raises no new

Difference	Proposed device	Predicate device K171158; K092309;	Performance Testing
(mm)		KD-612L: Φ2.6mm.	questions regarding safety and efficacy.
Working Length	5521: 1650mm,1950mm, 2300mm; 5522: 1650mm,1950mm; 5524: 1650mm,1950mm, 2300mm;	KD-655L: 1650mm; KD-620LR: 1650mm; KD-611lL: 1650mm;	
Cutting knife length	5521: 1.4mm, 2.1mm 5522: 4.0mm 5524: 3.0mm, 3.5mm	KD-655 L: 2.0mm; KD-620LR: 4.5mm; KD-611L: 4mm;	
Tip diameter	5524: Φ1.2mm, Φ1.7mm	KD-612: Φ2.2mm	
Materials or substances in contact with the same human tissue or body fluids	PTFE, SUS304, SUS303	No information.	Biocompatibility tests reports. The difference raises no new questions regarding safety and efficacy.

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The Electrosurgical System meets all design specifications and medical device standards for electrical safety and EMC (IEC 60601), biocompatibility (ISO 10993) and sterility (ISO 11135). The performance in ex-vivo and in-vivo meets the design specification and shows substantial equivalence to the predicated devices.

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.