October 5, 2021

Hangzhou AGS MedTech Co., Ltd.
Yanping Fu
RA Supervisor
Building 5, Building 6, No. 597 Kangxin Road Yuhang District
Hangzhou, Zhejiang 311106
CHINA

Re: K210406
Trade/Device Name: Bipolar Coagulation Forceps
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KGE
Dated: August 20, 2021
Received: August 26, 2021

Dear Yanping Fu:

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
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)*
/ K210406

Device Name
Bipolar Coagulation Forceps

Indications for Use *(Describe)*
Bipolar Coagulation Forceps have been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

Type of Use *(Select one or both, as applicable)*

[X] 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, 311106 Hangzhou, Zhejiang, 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:	Feb. 07, 2021

5.2 Proposed Device

Trade Name:	/
Device Name:	Bipolar Coagulation Forceps
Common Name:	Bipolar Coagulation Forceps
Regulation class:	Class II
Regulation Number:	876.4300
Regulation Description:	Endoscopic electrosurgical unit and accessories.
Review Panel:	Gastroenterology/Urology
Product Code:	KGE
Product Code Name:	Forceps, Biopsy, Electric

5.3 Predicate Device

Trade Name:	Coagrasper™
Device Name:	Single-use Electrosurgical Hemostatic Forceps
Common Name:	Electrosurgical Hemostatic Forceps Series
510(k) Number:	K062517
Regulation class:	Class II
Regulation Number:	876.4300
Regulation Description:	Endoscopic electrosurgical unit and accessories.
Review Panel:	Gastroenterology/Urology
Product Code:	KGE
Product Code Name:	Forceps, Biopsy, Electric

5.4 Device Description

The Bipolar Coagulation Forceps described in this submission are a sterile, single use

devices compatible with the working channel of endoscope. The device is used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

5.5 Indication for use statement

Bipolar Coagulation Forceps have been designed to be used with endoscopes to cauterize and coagulate or to perform hemostasis using high-frequency current within the digestive tract.

5.6 Comparison of Technology Characteristics

Our proposed device Bipolar Coagulation Forceps is substantially equivalent to the predicate devices. The differences between the Bipolar Coagulation Forceps 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
Common name		Bipolar Coagulation Forceps	Single-use electrosurgical hemostatic forceps	/
Trade name		/	Coagrasper™	/
Model number		5461, 5462, 5463, 5464	KD-410LR	/
510(k) submitter		Hangzhou AGS MedTech Co., Ltd.	Olympus Medical Systems Corporation	/
510(k) number		/	K062517	/
Technical	Principles of operation	Bipolar Coagulation Forceps is an applied part of electrosurgical generator, using bipolar high-frequency current delivered by the electrosurgical generator to cauterize and coagulate or to perform hemostasis within the digestive tract. We designed two electrodes (two forceps cup) of opposite polarity attached to the tip of its sheath. The high-frequency electricity flows from one forceps cup to another forceps cup. No neutral electrode is needed.	Monopolar Single-use electrosurgical hemostatic forceps is an applied part of electrosurgical generator, using monopolar high-frequency current delivered by the electrosurgical generator to cauterize and coagulate or to perform hemostasis within the digestive tract. The high-frequency electricity flows from the active electrode (forceps) to the neutral electrode placed on patient skin.	Similar. Both Bipolar Coagulation Forceps and Monopolar Single-use Electrosurgical Hemostatic Forceps are applied part of electrosurgical generator. Bipolar Coagulation Forceps has two electrodes (two forceps cup) of opposite polarity attached to the tip of its sheath. Thermal effect study and animal study had been conducted to demonstrate substantial

Item		Proposed device	Predicate device	Comparison
				equivalence, please refer to Section 18.2 Thermal Effect study and 19 Animal study of this submission.
	Structure	Bipolar Coagulation Forceps consists of Handle part, plug, sheath and forceps part.	Electrosurgical hemostatic forceps consists of handle part, plug, sheath, forceps part, and A cord.	Similar. Electrosurgical hemostatic forceps has a A cord while Bipolar coagulation forceps don't have.
	Energy Use	Bipolar Radio Frequency Current	Monopolar Radio Frequency Current	Different. Thermal effect study and animal study had been conducted to demonstrate substantial equivalence, please refer to Section 18.2 Thermal Effect study and 19 Animal study of this submission.
	Sheath tube	2.5mm	2.75mm	Similar.
	Span length	4.0mm, 5.0mm, 6.5mm, 7.0mm	5.0mm	Similar. The difference will not raise any question of safety and effectiveness. Our proposed device has more choice on span

Item		Proposed device	Predicate device	Comparison
				length for operators, operators could choose based on their clinical needs.
	Minimum Working Channel:	3.2mm	2.8mm	Similar.
	Working length	1650mm, 1950mm, 2300mm	1650mm;	Similar. The difference will not raise any question of safety and effectiveness. Our proposed device has more choice on working length for operators, operators could choose based on their clinical needs.
Biological	Materials or substances in contact with the same human tissue or body fluids	Plastic PTFE, Stainless Steel 304, Stainless Steel N, PEEK450-GL30, Ceramic, Stainless Steel 630.	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 10993-10: 2010; Intracutaneous Reactivity Test: ISO 10993-10: 2010; Acute Systemic Toxicity Test: ISO 10993-11:2017; Pyrogenicity: ISO 10993-11:2017;	No exact information.	

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The Bipolar Coagulation Forceps 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.

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 Bipolar Coagulation Forceps is substantially equivalent to the predicate devices.