February 8, 2021

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: K201121
Trade/Device Name: Sphincterotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS

Dear Chunqi Han:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 5, 2021. Specifically, FDA is updating this SE Letter with a signature as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Thelma Valdes, OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, 301-796-9621, Thelma.valdes@fda.hhs.gov.

Sincerely,

Thelma I. Valdes -S
Date: 2021.02.08 12:47:14 -05'00'

Thelma Valdes, Ph.D.
Acting 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

February 5, 2021

Hangzhou AGS MedTech Co., Ltd.
Chunqi Han
R&D Director
Building 5, Building 6, No.597 Kangxin Road
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Re: K201121
Trade/Device Name: Sphincterotome
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: April 22, 2020
Received: April 27, 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,

Thelma Valdes, PhD
Acting Assistant Director
Obesity and Hepatobiliary Devices Team
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)*

K201121

Device Name
Sphincterotome

Indications for Use *(Describe)*

The Sphincterotome is indicated for use in the cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Spincter of Oddi. 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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PRAStaff@fda.hhs.gov

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AGS MEDTECH 安杰思医学

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:	Apr. 22, 2020

5.2 Proposed Device

Trade Name:	Sphincterotome
Device Name:	Sphincterotome
Common Name:	Sphincterotome
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:	Howell D.A.S.H.®
Device Name:	Sphincterotome with DomeTip
Common Name:	Sphincterotome with DomeTip
510(k) Number:	K172665
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)

Trade Name:	Huibregtse®
Device Name:	Needle knife
Common Name:	Needle knife
510(k) Number:	K040981
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)

5.4 Device Description

The sphincterotome described in this submission are a sterile, single use devices compatible with the working channel of endoscope. The device consists of a long plastic tube with a wire running the length of its interior. A small portion of that wire is exposed at its distal end. The roof of the papilla is opened by passing high-frequency current through the wire, exposing the biliary or pancreatic orifices for selective cannulation. For 50910 series, there's preloaded guide wire.

5.5 Indication for use statement

The Sphincterotome is indicated for use in the cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Spincter of Oddi. The device is supplied sterile and intended for single use only.

5.6 Comparison of Technology Characteristics

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

Table 5.6-1 Comparison of technical characteristics

Item		Proposed device	Predicate device	Comparison
Common name		Sphincterotome	Sphincterotome with DomeTip	Similar
Trade name		Sphincterotome	D.A.S.H	/
Model number		5096, 5098, 50910	DASH-21, DASH-21-480, DASH-1, DASH-260, DASH-480, DASH-ACRO-25-450, DASH-35, DASH-ACRO-35-260, DASH-35-480, DASHACRO-35-450	/
510(k) submitter		Hangzhou AGS MedTech Co., Ltd.	Wilson-Cook Medical, Inc.	/
510(k) number		/	K172665	/
Clinical	Intended use	The Sphincterotome is indicated for use in the cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Spincter of Oddi. The device is supplied sterile and intended for single use only.	Howell D.A.S.H.® Sphincterotome with DomeTip® (Cook Reference Part Numbers DASH-21, DASH-21-480, DASH-1, DASH-260, DASH-480, DASH-ACRO-25-450, DASH-35, DASH-ACRO-35-260, DASH-35-480, DASHACRO-35-450): This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP.	Same
Technical	Principles of operation	Monopolar Sphincterotome manufactured is an applied part of electrosurgical generator, using monopolar high-frequency current delivered by the	Monopolar Sphincterotome manufactured is an applied part of electrosurgical generator, using monopolar high-frequency current delivered by the electrosurgical generator for sphincterotomy with the electrode. The high-	Same

Item		Proposed device	Predicate device	Comparison
		electrosurgical generator for sphincterotomy with the electrode. The high-frequency electricity flows from the active electrode to the neutral electrode placed on patient skin.	frequency electricity flows from the active electrode to the neutral electrode placed on patient skin.	
	Energy Use	Monopolar Radio Frequency Current	Monopolar Radio Frequency Current	Same
	Preloaded Wire Guide or not	Preloaded Wire Guide: 50910 Not preloaded Wire Guide:5096, 5098;	Preloaded Wire Guide: DASH-21-480, DASH-ACRO-25-450, DASH-480, DASH-260, DASH-ACRO-35-260, DASH-35-480, DASHACRO-35-450; Not preloaded Wire Guide: DASH-21, DASH-1, DASH-35;	/
	Sheath tube	2.4mm	Catheter Size: 5.5Fr (≈1.8mm), 6Fr (≈2mm), 6.5Fr (≈2.1mm)	Similar
	Wire Guide Diameter	0.63mm, 0.89mm	Wire Guide Diameter inch: 0.021 (≈0.53mm), 0.025 (≈0.58mm), 0.035 (≈0.89mm);	Similar
	Minimum Accessory Channel:	2.8mm	2.8mm	Same
	Working length	1800mm	1960mm;	Similar
	Performance	①Injection performance; ②Compatibility with traction guide wire; ③Compatibility with Endoscope; ④X-ray detectability,	No information	Substantial equivalence. We conducted all the performance testing on our proposed device in comparison with our chosen

Item		Proposed device	Predicate device	Comparison
		⑤Visibility under endoscopy, ⑥Electric performance, ⑦Operation flexibility, ⑧Rotation performance;		predicate. All the test results show that the proposed device is substantial equivalence with the predicate. For bench tests reports, please refer to Section 18 of this submission.
		Connected firmly: ensure the device does not cause device breakage or detachment between joints.	Connected firmly: ensure the device does not cause device breakage or detachment between joints.	Substantial equivalence. We conducted Connected firmly on our proposed device in comparison with our chosen predicate. All the test results show that the proposed device is safer than our predicate device. For bench tests reports, please refer to Section 18 of this submission.
		Force to Bow	Force to Bow	Substantial equivalence. We conducted Force to Bow on our proposed device in comparison with our chosen predicate. All the test results show that the proposed device is as safe

Item		Proposed device	Predicate device	Comparison
				and effective as our predicate device. For bench tests reports, please refer to Section 18 of this submission.
		Orientation of Cutting Wire and Visualization of Cutting Wire testing: ensure for orientation and visualization of the cutting wire when endoscopically viewed.	Orientation of Cutting Wire and Visualization of Cutting Wire: ensure for orientation and visualization of the cutting wire when endoscopically viewed.	Substantial equivalence. We conducted Orientation of Cutting Wire and Visualization of Cutting Wire 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.
		Ink Validation testing: ensure for ink marking visualization when endoscopically viewed.	Ink visualization: ensure for ink marking visualization when endoscopically viewed.	Substantial equivalence. We conducted Ink visualization on our proposed device in comparison with our chosen predicate. All the test results show that the proposed device is as safe

Item		Proposed device	Predicate device	Comparison
				and effective as our predicate device. For bench tests reports, please refer to Section 18 of this submission.
		Fluoroscopic Visibility testing: ensure the end user is able to fluoroscopically visualize the location of the sphincterotome.	Fluoroscopic Visibility: ensure the end user is able to fluoroscopically visualize the location of the sphincterotome.	Substantial equivalence. We conducted Fluoroscopic Visibility 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.
Biolo-gical	Materials or substances in contact with the same human tissue or body fluids	Plastic PTFE, Stainless Steel 304, PET; Silicone oil, PTFE, Polyurethane, Medical grade hydrophilic coating;	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	No exact information.	

Item		Proposed device	Predicate device	Comparison
		10993-10: 2010; Acute Systemic Toxicity Test: ISO 10993-11:2017; Pyrogenicity: ISO 10993-11:2017;		
Single Use	/	Yes	Yes	Same
Shelf life and sterilization	/	Shelf life: 3 years Sterilization: EO Sterilization, SAL OF 10^{-6}	Shelf life: 3 years Sterilization: EO Sterilization	Same

Table 5.6-2 Comparison of technical characteristics

Item		Proposed device	Predicate device	Comparison
Common name		Sphincterotome	Needle knife	Similar
Trade name		Sphincterotome	Huibregtse®	/
Model number		5099	G24885/HPC-3	/
510(k) submitter		Hangzhou AGS MedTech Co., Ltd.	Wilson-Cook Medical, Inc.	Same
510(k) number		K201121	K040981	/
Clinical	Intended use	The Sphincterotome is indicated for use in the cannulation of the biliary ducts and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Spincter of Oddi. The device is supplied sterile and intended for single use only.	The Wilson-Cook USW Needleknife Papillotome is intended for accessing the common bile duct when standard cannulation methods have been exhausted. The USW Needleknife Papillotome is supplied sterile and intended for single use only.	Same

Item		Proposed device	Predicate device	Comparison
Technical	Principles of operation	Monopolar Sphincterotome manufactured is an applied part of electrosurgical generator, using monopolar high-frequency current delivered by the electrosurgical generator for sphincterotomy with the electrode. The high-frequency electricity flows from the active electrode to the neutral electrode placed on patient skin.	Monopolar Sphincterotome manufactured is an applied part of electrosurgical generator, using monopolar high-frequency current delivered by the electrosurgical generator for sphincterotomy with the electrode. The high-frequency electricity flows from the active electrode to the neutral electrode placed on patient skin.	Same
	Energy Use	Monopolar Radio Frequency Current	Monopolar Radio Frequency Current	Same
	Catheter Size	2.4mm-1.8mm	7Fr(2.33mm)-5Fr(1.67mm)	Same
	Wire Guide Diameter	0.63mm, 0.89mm	0.035 (≈0.89mm);	Similar
	Minimum Accessory Channel	2.8mm	2.8mm	Same
	Working length	1800mm	2000mm	Similar
	Performance	①Injection performance; ②Compatibility with traction guide wire; ③Compatibility with endoscope; ④Visibility under endoscopy; ⑤Electric performance; ⑥Operation flexibility; ⑦Connected firmly. ⑧Orientation of Cutting Wire and Visualization of Cutting Wire testing;	No information	Similar. Bench tests have been done for both the proposed device and predicate device. Please refer to Section 18 of this submission.

Item		Proposed device	Predicate device	Comparison
		⑨Ink Validation testing;		
Biolo-gical	Materials or substances in contact with the same human tissue or body fluids	Plastic PTFE, Stainless Steel 304;	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 information.	
Single Use	/	Yes	Yes	Same
Shelf life and sterilization	/	Shelf life: 3 years Sterilization: EO Sterilization, SAL OF 10^{-6}	Shelf life: 3 years Sterilization: EO Sterilization	Same

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The Sphincterotome 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 Sphincterotome is substantially equivalent to the predicate devices.