May 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: K222421
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 4, 2023
Received: April 4, 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,

Glenn B. Bell -S

Glenn B. Bell, Ph.D.
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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

51O(k) Number *(if known)*
K222421

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)*

IZ] Prescription Use (Part 21 CFR 801 Subpart D) D Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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:	May 2, 2023

5.2 Device Identification

Trade Name:	Sphincterotome
Device Name:	Sphincterotome
Common Name:	Sphincterotome
Regulation Class:	Class II
Regulation Number:	876.4300
Regulation Name:	Endoscopic electrosurgical unit and accessories.
Review Panel:	Gastroenterology/Urology
Product Code:	KNS
Product Code Name:	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)

5.3.1 Primary Predicate Device

Trade Name:	Autotome™ RX
Device Name:	Autotome RX Cannulating Sphincterotome
Common Name:	Sphincterotome
510(k) Number:	K013153
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)

5.3.2 Secondary Predicate Device

Trade Name:	Sphincterotome
Device Name:	Sphincterotome
Common Name:	Sphincterotome
510(k) Number:	K201121
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 is a sterile, single use device 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 papilla is opened by passing high-frequency current through the wire, exposing the biliary or pancreatic orifices for selective cannulation.

For non-exchangeable models, the sphincterotome is compatible with endoscopes with a working channel diameter not less than 2.8mm, and the recommended guide wire OD is 0.63mm (0.025inch) or 0.89mm (0.035inch);

For normal exchangeable models, there is a small hole on the sheath which is about 200mm far away from the distal end, it is used to insert the guide wire rapidly, the sphincterotome is compatible with endoscopes with a working channel diameter not less than 3.7mm, and the recommended guide wire OD is 0.63mm (0.025inch) or 0.89mm (0.035inch);

For C-type exchangeable models, there is an open channel on the sheath to rapid exchange the guide wire, the sphincterotome is compatible with endoscopes with a working channel diameter not less than 3.7mm, and the recommended guide wire OD is 0.63mm (0.025inch) or 0.89mm (0.035inch);

For 50910, 50913, 50916 and 50917 series, there's preloaded guide wire, the sphincterotome is compatible with endoscopes with a working channel diameter not less than 3.7mm, and the OD of preloaded guide wire is detailed in the device's label.

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 Sphincterotome	Predicate device (K013153)	Comparison
Common name		Sphincterotome	Sphincterotome	/
Trade name		Sphincterotome	Autotome™ RX	/
Model number		50912, 50913, 50917 series	M00545150, M00545160, M00545170, M00545180, M00545190, M00545200	/
510(k) submitter		Hangzhou AGS MedTech Co., Ltd.	Boston Scientific Corporation	/
510(k) number		/	K013153	/
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 Sphincterotome is indicated for use in the selective cannulation of the Common Bile Ducts (CBD) and the transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The Sphincterotome can also be used to inject contrast medium.	Similar. The equivalent device has a wider range of intended use than the proposed device.
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.	Sphincterotome 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
	Sheath tube	2.4mm	2.4mm	Same

Item		Proposed device Sphincterotome	Predicate device (K013153)	Comparison
	Wire Guide Diameter	0.63mm, 0.89mm	0.63mm, 0.89mm	Same
	Insulation protected	With/without	Without	Similar. This difference wouldn't influence the safety or performance if the device.
	Preloaded Wire Guide or not	Preloaded Wire Guide: 50913, 50917; Not preloaded Wire Guide: 50912;	No	Similar. Bench test has been conducted to demonstrate substantial equivalence, please refer to Section 18 bench performance testing.
	Compatible Minimum Accessory Channel	3.7mm	3.7mm	Same
	Working length	1800mm	2000mm	Different. Bench test has been conducted to demonstrate substantial equivalence, please refer to Section 18 bench performance testing.
	Performance	Injection performance, Compatibility with traction guide wire, Compatibility with endoscope, Ray detectability, Visibility under endoscopy, Electric performance,	Unknown	Same. Bench test has been conducted to demonstrate substantial equivalence, please refer to Section 18 bench performance testing.

Item		Proposed device Sphincterotome	Predicate device (K013153)	Comparison
		Operation flexibility, Connected firmly, Rotation performance, Force to Bow, Orientation of Cutting Wire and Visualization of Cutting Wire, Ink Validation; Cutting rate; Energy dose analyses;		
Biological	Materials or substances in contact with the same human tissue or body fluids	Plastic PTFE, Stainless Steel 304, PTFE; Silicone oil, PTFE, Polyurethane, Medical grade hydrophilic coating;	Unknown	Different. Biocompatibility tests have been done. 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;	Unknown	
Single Use		Yes	Yes	Same
Shelf life and sterilization		Shelf life: 18 months; Sterilization: EO Sterilization, SAL of 10^{-6};	Shelf life: 3 years; Sterilization: EO Sterilization;	Different. Accelerated aging tests have been done. The proposed device can support the claimed shelf life.

Table 5.6-2 Comparison of technical characteristics

Item		Proposed device Sphincterotome	Predicate device (K201121)	Comparison
Common name		Sphincterotome	Sphincterotome	/
Trade name		Sphincterotome	Sphincterotome	/
Model number		5091, 5093, 5094, 5096, 5098, 5099, 50910, 50912, 50913, 50916, 50917 series	5096, 5098, 5099, 50910 series	/
510(k) submitter		Hangzhou AGS MedTech Co., Ltd.	Hangzhou AGS MedTech Co., Ltd.	/
510(k) number		/	K201121	/
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 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.	Same
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
	Preloaded Wire Guide or Not	Preloaded Wire Guide: 50910, 50913, 50916, 50917; Not preloaded Wire Guide: 5091, 5093, 5094, 5096,	Preloaded Wire Guide: 50910 Not preloaded Wire Guide: 5096, 5098, 5099;	Same

Item		Proposed device Sphincterotome	Predicate device (K201121)	Comparison
		5098, 5099, 50912;		
	Sheath tube	2.4mm	2.4mm	Same
	Wire Guide Diameter	0.63mm, 0.89mm	0.63mm, 0.89mm	Same
	Compatible Minimum Accessory Channel	5091, 5094, 5096, 5099: 2.8mm; 5093, 5098, 50910, 50912, 50913, 50916, 50917: 3.7mm;	5096, 5099: 2.8mm; 5098, 50910: 3.7mm;	Same
	Working Length	1800mm	1800mm	Same
	Performance	Injection performance, Compatibility with traction guide wire, Compatibility with endoscope, Ray detectability, Visibility under endoscopy, Electric performance, Operation flexibility, Connected firmly, Rotation performance, Force to Bow, Orientation of Cutting Wire and Visualization of Cutting Wire, Ink Validation; Cutting rate; Energy dose analyses;	Injection performance, Compatibility with traction guide wire, Compatibility with Endoscope, Ray detectability, Visibility under endoscopy, Electric performance, Operation flexibility, Connected firmly, Rotation performance; Force to Bow, Orientation of Cutting Wire and Visualization of Cutting Wire, Ink Validation;	Same. Bench test has been conducted to demonstrate substantial equivalence, please refer to Section 18 bench performance testing.

Item		Proposed device Sphincterotome	Predicate device (K201121)	Comparison
Biological	Materials or substances in contact with the same human tissue or body fluids	Plastic PTFE, Stainless Steel 304, PTFE; Silicone oil, PTFE, Polyurethane, Medical grade hydrophilic coating;	Plastic PTFE, Stainless Steel 304, PET; Silicone oil, PTFE, Polyurethane, Medical grade hydrophilic coating;	Same. Biocompatibility tests have been done. 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;	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;	
Single Use		Yes	Yes	Same
Shelf life and sterilization		Shelf life: 18 months; Sterilization: EO Sterilization, SAL of 10^{-6};	Shelf life: 3 years; Sterilization: EO Sterilization, SAL of 10^{-6};	Different. Accelerated aging tests have been done. The proposed device can support the claimed shelf life.

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.