February 27, 2020

Hangzhou AGS MedTech CO., Ltd
Yangping Fu
RA Specialist
Building 5, Building 6, Kangxin Road No.597
Yuhang District
311106 Hangzhou, Zhejiang
CHINA

Re: K190032
Trade/Device Name: Disposable Sclerotherapy Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBK
Dated: February 20, 2020
Received: February 26, 2020

Dear Yangping 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,

Shanil P. Haugen, 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

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)*
K190032

Device Name
Disposable Sclerotherapy Needle

Indications for Use *(Describe)*
The Disposable Sclerotherapy Needle is intended for endoscopic injection into the gastrointestinal mucosa.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 5, Building 6, No.597 Kangxin Road, Yuhang District, 311106 Hangzhou, Zhejiang, China
Establishment Registration Number:	3010288205
Owner/Operator Number:	10052959
Contact Person:	Yanping Fu Phone: +86-571--87671223 Fax: +86-571--87671225 Email:fuyp@bioags.com
Date Prepared:	Jan 3, 2019

5.2 Proposed Device

Trade Name:	Disposable Sclerotherapy Needle
Common Name:	Disposable Sclerotherapy Needle
Classification:	Class II
Regulation Number:	876.1500
Regulation Name:	Endoscope and accessories
Product Code:	FBK
Product Code Name:	Endoscopic Injection Needle, Gastroenterology-Urology

5.3 Predicate Device

Trade Name:	Injection Therapy Needle Catheter
Common Name:	Injection Therapy Needle Catheter
Manufacturer:	Boston Scientific Corporation
510(k) Number:	K171454
Classification:	Class II
Regulation Number:	876.1500
Regulation Name:	Endoscope and accessories
Product Code:	FBK
Product Code Name:	Endoscopic Injection Needle, Gastroenterology-Urology

5.4 Device Description

The Disposable Sclerotherapy Needle device consists of: Luer connector, handle, molding metal tube, Inner sheath connection limit tube, Fixing sleeve, Outer sheath, Inner sheath, connection tube, metal cap, needle. EO Sterilization and use for single use only. The material expected to come into contact with the patient is SUS304、

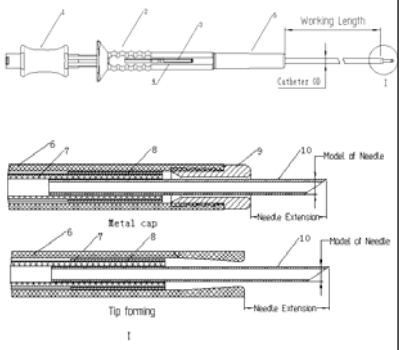
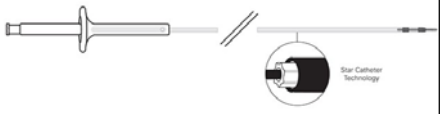
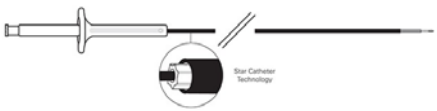
SUS303、PP/PE.

5.5 Indication for Use:

The Disposable Sclerotherapy Needle is intended for endoscopic injection into the gastrointestinal mucosa.

5.6 Comparison of Technology Characteristics

The Disposable Sclerotherapy Needle has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Boston Scientific Corporation's Injection Therapy Needle Catheter, K171454. The differences between the proposed device and the predicate devices do not raise any questions regarding its safety and effectiveness. The differences are listed in the table below.

Item	Proposed Device	Predicate device(K171454)	Comment
Indication for Use	The Disposable Sclerotherapy Needle is intended for endoscopic injection into the gastrointestinal mucosa.	The Interject ™ Injection Therapy Needle Catheter is used for endoscopic injection into gastrointestinal mucosa and submucosa to: ➢ introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential bleeding lesions in the digestive system ➢ aid in Endoscopic Mucosal Resection (EMR), Endoscopic Submucosal Dissection (ESD), or polypectomy procedures ➢ control non-variceal hemorrhage	Similar: Both can be used for gastrointestinal mucosal injection.
Configuration	Luer connector, handle, molding metal tube, Inner sheath connection limit tube, Fixing sleeve, Outer sheath, Inner sheath, connection tube, metal cap, needle	The Interject™ Injection Therapy Needle Catheter is a catheter that consists of a handle with a hub for injection, a catheter sheath, and a needle.	Similar
Photographs	Disposable Sclerotherapy Needle:  5311 Series（with tip forming）:  	Interject Clear Single-Use Injection Therapy Needle Catheters:   Interject Contrast Single-Use Injection Therapy Needle Catheters: 	Similar

Item	Proposed Device	Predicate device(K171454)	Comment
	5311 Series (with metal cap):  5313 Series (with metal cap): 		
Sheath diameter	2.4mm	1.8mm,2.3mm	Similar
Needle size:	21G, 22G, 23G, 24G, 25G	23G, 25G	Similar
Outer tubing	For 5311 series: PP; For 5313 series: SUS 304 covered by PE.	For clear sheath design: unknown; For contrast sheath design: unknown.	May be different：We conducted a biocompatibility evaluation of the device. The results show the device is safe in the aspect of biocompatibility evaluation.
Working Length	1600mm, 2000mm, 2300mm	2000mm ,2400mm	Similar
Packaging	Single-use EO sterilized Tyvek pouch	Single-use EO sterilized.	Similar

Item	Proposed Device	Predicate device(K171454)	Comment
	with one device per pouch.		
Materials	Luer connector: PC; Handle: PC; Molding metal tube: SUS304; Inner sheath connection limit tube: PTFE; Fixing sleeve: ABS; Outer sheath: PP(5311series); SUS 304 and PE (5313 series); Inner sheath: PP; Connection tube: SUS 304; Metal cap: SUS303; Needle: SUS304. The material expected to come into contact with the patient is SUS304, SUS303 and PP, or SUS304、SUS303 and PE.	Unknown	Different: This difference does not alter the suitability of the proposed device for its intended use. We conducted a biocompatibility evaluation of the device. The results show the device is safe in the aspect of biocompatibility evaluation.
Principle of operation	The outer sheath of the product is inserted into the endoscope clamp. When the front part of the outer sheath tube is placed on the lesion site, push the Luer connector, the needle tube is exposed to the outer sheath, and the needle is inserted into the lesion site, then normal saline injection.	The catheter sheath of the product is inserted into the endoscope clamp. When the front part of the catheter sheath is placed on the lesion site, push the handle with a hub for injection, the needle is exposed to the catheter sheath, and the needle is inserted into the lesion site, then drug injection.	Similar

5.7 Applicable Guidance Document

NA

5.8 Performance Data

The proposed device meets the requirements of ISO 10993 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing”, ISO 11135-1 “Sterilization of Health Care products Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices”, and ISO 10993-7 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals”

The following bench tests were performed on Disposable Sclerotherapy Needle: Appearance, Physical properties. The results of all testing were passing.

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 Disposable Sclerotherapy Needle is substantially equivalent to Boston Scientific Corporation’s Injection Therapy Needle Catheter, K171454.