February 23, 2022

Zhejiang Chuangxiang Medical Technology Co., LTD.
Lucius Long, RA Manager
Building 50, No. 650
Hongfeng Road Donghu Street
Yuhang District, Hangzhou, 311100
CHINA

Re: K212668
Trade/Device Name: Sclerotherapy Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: August 24, 2021
Received: January 27, 2022

Dear Lucius Long:

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.
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)*
K212668

Device Name
Sclerotherapy Needle

Indications for Use *(Describe)*
The device is used for endoscopic injection into gastrointestinal mucosa, or to endoscopically introduce a sclerosing agent into selected sites to control actual or potential bleeding lesions in the digestive system.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Zhejiang Chuangxiang Medical Technology Co., LTD.

510(k) Summary(21CFR 807.92)

1. Submitter's information

Name: Zhejiang Chuangxiang Medical Technology Co., LTD.

Address: Room 101,201,301,401,501, Building 50, No.650 Hongfeng Road Donghu Street, Yuhang District, Hangzhou City, Zhejiang Province， 311100， P.R. China

Contact person: Lucius.Long
Email： lucius.long@med-nova.com
Telephone: 86-571-89167088
Fax: 86-571-89167086

2. Date of Submission

09-Aug- 2021

3. Device

Trade/Device Name: Sclerotherapy Needle
Regulation name: Endoscope and accessories
Regulation class: II
Regulation number:876.1500
Panel: Gastroenterology/Urology
Product code: FBK

4. Predicative device

4.1) 510(k) Number: K190032
Device Name: Disposable Sclerotherapy Needle

5. Device description

The Sclerotherapy Needle device consists of Luer connector, handle, sheath, infusion tube, fixed button connection tube and needle. EO sterilization and use for single use only.

The Sclerotherapy Needle device is designed to pass through the channel of endoscope to mark the lesions of the digestive tract and use it for injection. Compatibility with endoscopes, working lengths are 1200mm,1800mm, 2000mm, 2300mm, and the minimum working channel is ϕ 2.8 mm.

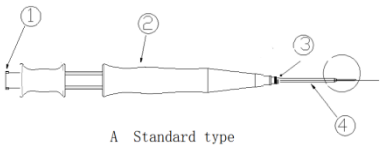
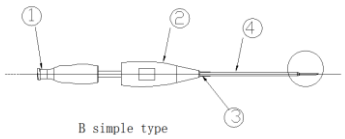
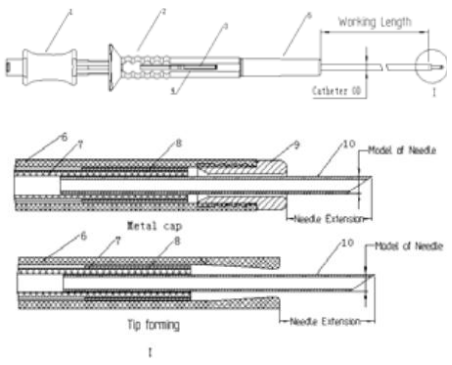
6. Indications for use

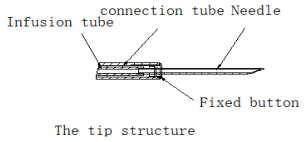
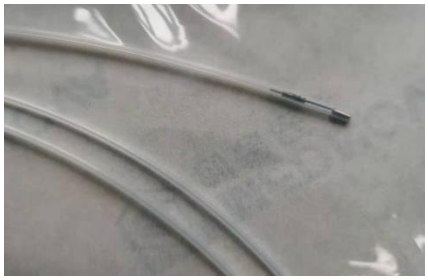
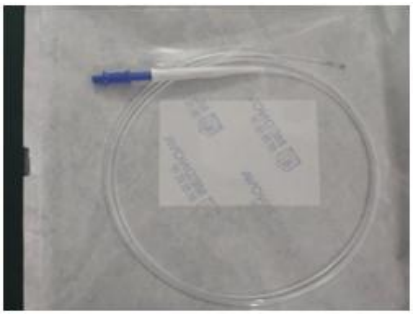
The device is used for endoscopic injection into gastrointestinal mucosa, or to endoscopically introduce a sclerosing agent into selected sites to control actual or potential bleeding lesions in the digestive system.

7. Comparison of Technological Characteristics:

The Sclerotherapy Needle has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Hangzhou AGS's Disposable Sclerotherapy Needle ,K190032.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	Comparison to Predicate Devices
Device name	Sclerotherapy Needle	Disposable Sclerotherapy Needle	/
Indications for Use	The device is used for endoscopic injection into gastrointestinal mucosa, or to endoscopically introduce a sclerosing agent into selected sites to control actual or potential bleeding lesions in the digestive system.	The Disposable Sclerotherapy Needle is intended for endoscopic injection into the gastrointestinal mucosa.	Substantial Equivalence
Configuration	Luer connector,Handle, Infusion tube,Sheath,Fixed button,Connection tube,Needle	Luer connector, handle, molding metal tube, Inner sheath connection limit tube, Fixing sleeve, Outer sheath, Inner sheath, connection tube, metal cap, needle	Similar
Photographs	Sclerotherapy Needle:  1、Luer connector 2、Handle 3、Drive Pipe 4、Sheath  1、Luer connector 2、Handle 3、Drive Pipe 4、Sheath	Disposable Sclerotherapy Needle:  5311 Series（with tip forming）:	Similar

	 The tip structure With fixed button：   Without fixed button：  	  5311 Series (with metal cap):  5313 Series (with metal cap): 	
Sheath diameter	1.8mm,2.4mm	2.4mm	Similar
Needle size:	19G,21G, 23G,25G	21G, 22G, 23G, 24G, 25G	Similar
Outer tubing	PTFE	For 5311 series: PP; For 5313 series: SUS 304 covered by PE.	Similar： We conducted a Biocompatibility

			evaluation of the device. The results show the device is safe in the aspect of biocompatibility evaluation
Working Length	1200mm,1800mm, 2000mm, 2300mm	1600mm, 2000mm, 2300mm	Similar
Packaging	Single-use EO sterilized paper-plastic pouch with one device per pouch.	Single-use EO sterilized Tyvek pouch with one device per pouch.	Similar
Materials	Luer connector: ABS Handle: ABS Infusion tube: PP Sheath: PTFE Fixed button: Y12Cr18Ni9Cu3 Connection tube: SUS304(06Cr19Ni10） Needle:X5CrNi18-9	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.	Similar
Principle of operation	The catheter sheath of the product is inserted into the endoscope channel. When the front part of the catheter sheath is placed on the lesion site, push the Luer connector for injection, the needle is exposed to the catheter sheath, and the needle is inserted into the lesion site, then drug injection.	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.	Similar

8. Applicable Guidance Document

NA

9. Performance Data

The proposed device meets the requirements of ISO 10993 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing”, ISO 11135:2014 “Sterilization of Health Care products Ethylene Oxide - 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 Sclerotherapy Needle: Appearance, Physical properties. The results of all testing were passing.

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusions

Chuangxiang medical has demonstrated that the proposed device Sclerotherapy Needle is substantially equivalent to Hangzhou AGS MedTech CO., Ltd. currently marketed Disposable Sclerotherapy Needle (K190032).