November 9, 2023

Zhejiang Soudon Medical Technology Co.,Ltd
℅ Nick Wang
RA Specialist
Shanghai Vanhe Consulting Co., Ltd
2F, Building No.1, 3938 Huqingping Road, Qingpu District
Shanghai, 201703
China

Re: K232442
Trade/Device Name: Disposable Endoscope Injection Needles
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: August 11, 2023
Received: August 14, 2023

Dear Nick Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -S

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)*
K232442

Device Name
Disposable Endoscope Injection Needles

Indications for Use *(Describe)*
Disposable Endoscope Injection Needles are used with endoscope to perform endoscopic vascular or submucosal injection in the GI tract.

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.

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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.

1. Submitter

Submitted by:	Zhejiang Soudon Medical Technology Co.,Ltd Address:Room 302-1,Floor 3, Building 4, No.1 Nangonghe Road, Donghu Street, Linping District, Hangzhou 311100 Zhejiang, China
Contact Person:	Nick Wang RA Specialist Shanghai Vanhe Consulting Co., Ltd Address: 2F, Building No.1, 3938 Huqingping Road, Qingpu District, Shanghai, China. Phone: 0086-13585860297 Email: vanheconsulting@126.com
Date Prepared:	August 11, 2023

Device

Device Name:	Disposable Endoscope Injection Needles
Classification Name:	Endoscopic Injection Needle, Gastroenterology-Urology
Regulatory Class:	II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	FBK

Predicate Device

Device Name:	Disposable Sclerotherapy Needle, K190032
Manufacturer:	Hangzhou AGS MedTech CO., Ltd
Classification Name:	Endoscopic Injection Needle, Gastroenterology-Urology
Regulatory Class:	II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	FBK

2. Device Description

The Disposable Endoscope Injection Needles consist of a Sliding handle, Handle, Cap,

Sheath, Inner Tube, Guide Tube, Connecting tube, Needle, and Tip (only Type B). It is available in a variety of configurations with varying needle lengths, gauges and working lengths. Type A and Type B are included in this submission.

3. Indication for Use:

Disposable Endoscope Injection Needles are used with endoscope to perform endoscopic vascular or submucosal injection in the GI tract.

4. Comparison of Technological Characteristics

The Disposable Endoscope Injection Needles has substantially equivalent device design, configuration, packaging fundamental technology, sterilization process and intended use as those featured in the predicate device Hangzhou AGS MedTech CO., Ltd '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	Disposable Endoscope Injection Needles(**Proposed Device**)	Disposable Sclerotherapy Needle, K190032	Discussion
Indication for Use	Disposable Endoscope Injection Needles are used with endoscope to perform endoscopic vascular or submucosal injection in the GI tract.	The Disposable Sclerotherapy Needle is intended for endoscopic injection into the gastrointestinal mucosa.	Same
Outer Diameter	2.3mm	2.4mm	Same
Needle Gauge	21G, 23G, 25G	21G, 22G, 23G, 24G, 25G	Similar
Working Length	1800mm, 2300mm	1600mm, 2000mm, 2300mm	Similar
SAL	10^{-6}	10^{-6}	Same
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	
Sterilization Method	EO Sterilization	EO Sterilization	Same

5. Non-clinical 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 Endoscope Injection Needles: Appearance, Physical properties. The results of all testing were passing.

6. Clinical Test Data

No Clinical Study is included in this submission.

7. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Zhejiang Soudon Medical Technology Co.,Ltd has demonstrated that proposed device Disposable Endoscope Injection Needles is substantially equivalent to Hangzhou AGS MedTech CO., Ltd ’s currently marketed Disposable Sclerotherapy Needle, K190032.