August 19, 2022

Yangzhou Fartley Medical Instrument Technology Co., Ltd.
℅ Ethan Liu
RA Specialist
Shanghai Thinkwell Consulting Co., Ltd
Room 211/6F, Xinling Road, Minhang District
Shanghai, Shanghai 201100
CHINA

Re: K220292
Trade/Device Name: Disposable Endoscope Injection Needle
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBK
Dated: July 11, 2022
Received: July 18, 2022

Dear Ethan Liu:

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)*
K220292

Device Name
Disposable Endoscope Injection Needle

Indications for Use *(Describe)*
The Disposable Endoscope Injection Needle 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.

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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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:	Yangzhou Fartley Medical Instrument Technology Co., Ltd. Address:Beizhou Road, Lidian Town, Guangling District, Yangzhou 225106 Jiangsu, China
Contact Person:	Ethan Liu RA Specialist Shanghai Thinkwell Consulting Co., Ltd Address: Room 211/6F, Xinling Road, Minhang Districtt, Shanghai, China. Phone: 0086-15216699240 Email: xtdeepwater@126.com
Date Prepared:	July 5, 2022

5.2 Device

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

5.3 Predicate Device

Device Name:	Interject™ Injection Therapy Needle Catheter K171454
Manufacturer:	Boston Scientific Corporation
Classification Name:	Endoscopic Injection Needle, Gastroenterology-Urology
Regulatory Class:	II
Regulation Number:	21 CFR 876.1500
Regulation Name：	Endoscope and Accessories
Product Code:	FBK

5.4 Device Description

The Disposable Endoscope Injection Needle consists of Sheath, Handle buckle,

Handle, Booster tube, Handle end cap, Outer tube, Inner tube, Metal end cap and injection needle tip. It is available in a variety of configurations with varying needle lengths, gauges and working lengths.

5.5 Indication for Use:

The Disposable Endoscope Injection Needle 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.

5.6 Comparison of Technological Characteristics

The Disposable Endoscope Injection 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	Disposable Endoscope Injection Needle(**Proposed Device**)	Interject™ Injection Therapy Needle Catheter K171454	Discussion
Indication for Use	The Disposable Endoscope Injection Needle 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	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;	Same

Item	Disposable Endoscope Injection Needle(**Proposed Device**)	Interject™ Injection Therapy Needle Catheter K171454	Discussion
	Mucosal Resection (EMR), Endoscopic Submucosal Dissection (ESD), or polypectomy procedures; • control non-variceal hemorrhage.	• aid in Endoscopic Mucosal Resection (EMR), Endoscopic Submucosal Dissection (ESD), or polypectomy procedures; • control non-variceal hemorrhage.	
Configuration(Including Material)	The Disposable Endoscope Injection Needle consists of Sheath, Handle buckle, Handle, Booster tube, Handle end cap, Outer tube, Inner tube, Metal end cap and injection needle tip	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	Substantially equivalent
Needle Gauge	19G, 22G, 23G, 25G	23G, 25G	Similar
Out Diameter(mm)	1.8, 2.4	1.8, 2.3	Similar
Working Length(mm)	600, 1200, 1600, 1800,2300, 2500	2000, 24000	Similar
SAL	10^{-6}	10^{-6}	Same
Biocompatibility	Comply with ISO 10993-1	Comply with ISO 10993-1	Same
Sterilization Method	EO Sterilization	EO Sterilization	Same

5.7 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 Needle: Appearance, Dimension, performance, Connection strength, Leakage, Cleanliness,

Compatibility, Puncture force,Corrosion resistance,Patency of lumen, Durability, Stiffness test of needle, Resistance of needle to breakage, Positive pressure liquid leakage, Sub-atmospheric pressure air Leakage, Stress cracking, Resistance to separation from axial load, Resistance to overriding and Resistance to separation from unscrewing and flow rate. The results of all testing were passing.

5.8 Clinical Test Data

No Clinical Study is included in this submission.

5.9 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, Yangzhou Fartley Medical Instrument Technology Co., Ltd. has demonstrated that proposed device Disposable Endoscope Injection Needle is substantially equivalent to Boston Scientific Corporation's currently marketed Interject™ Injection Therapy Needle Catheter K171454.