October 4, 2024

Promisemed Hangzhou Meditech Co., Ltd.
Yang Zearou
Regulatory Affairs Manager
No. 1388 Cangxing Street
Cangqian Community, Yuhang District
Hangzhou City, 311121
China

Re: K240675
Trade/Device Name: Endoscopic Injection Needles
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBK
Dated: September 6, 2024
Received: September 6, 2024

Dear Yang Zearou:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shanil P. Haugen -S

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
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240675

Device Name

Endoscopic Injection Needles

Indications for Use *(Describe)*

It is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varices and for submucosal dye marking 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.

Promisemed Hangzhou Meditech Co., Ltd.
No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, P. R. China.

510(k) Summary

Date prepared: 2024-03-08

1. Manufacturer *[21 CFR 807.92 (a) (1)]*	
Name	Promisemed Hangzhou Meditech Co., Ltd.
Address	No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China.
Contact Person	Zearou Yang
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2. Device *[21 CFR 807.92 (a) (2)]*	
Name	Endoscopic Injection Needles
Common Name	Endoscopic Injection Needles
Classification Name	Endoscope and accessories
Regulation Number	876.1500
Class	Class II
Product Code	FBK
3. Legally Marketed Predicate Device *[21 CFR 807.92 (a) (3)]*	
Predicate Name	Single Use Injection Needle
510(k) Number	K210917
Product Code	FBK
Reference Devices	No reference devices were used in this submission.
4. Device Description *[21 CFR 807.92 (a) (4)]*	
It is a flexible, sterile, sharp bevel-edged, hollow tubular device intended to be manually-operated through a compatible endoscope to perform needle functions (e.g., injection) during endoscopy. It is designed with appropriate shape, materials and gauge to function through the working channel of an endoscope. This is a single-use device.	
5. Indication for use *[21 CFR 807.92 (a) (5)]*	
It is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varices and for submucosal dye marking in the GI tract.	
6. Indications for Use Comparison *[21 CFR 807.92 (a) (5)]*	
No difference.	

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7. Comparison of Technological Characteristic *[21 CFR 807.92 (a) (6)]*

Compared with the predicate device, the subject device is identical in mechanism of action, materials, dimension, sterilization method and biocompatibility. The subject device has the same performance specifications except for Outer sheath diameter, Minimal working channel and working length. Through performance bench testing, the subject device and the predicate device demonstrated to be substantially equivalent. At a high level, the subject and predicate devices are based on the following same technological elements:

Specification	Subject Device	Predicate Device(K210917)	Discussion of difference
Trade Name	Endoscopic Injection Needles	Single Use Injection Needle	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd.	Anrei Medical (Hangzhou) Co., Ltd.	
Device Class	Class II	Class II	No difference
Product Code	FBK	FBK	No difference
Regulation number	21 CFR 876.1500	21 CFR 876.1500	No difference
Prescription/over-the-counter use	Prescription	Prescription	No difference
Indications for Use	It is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varices and for submucosal dye marking in the GI tract.	It is to be used in conjunction with an endoscope to perform endoscopic injections, such as for the treatment of esophageal and gastric varices and for submucosal dye marking in the GI tract.	No difference
Environment of use	Healthcare facility/hospital	Healthcare facility/hospital	No difference
Single Use	Yes	Yes	No difference
Performance			
Needle tube size	21G, 23G, 25G	21G, 23G, 25G	No difference
Needle tube length	4mm, 6mm	4mm, 6mm	No difference
Outer sheath diameter	1.8mm, 2.4mm	2.4mm	Difference. Within the range. It does not introduce any new concerns for safety or efficacy which has been confirmed performance testing.
Minimal working channel	Φ2.0mm or Φ2.8mm	Φ2.8mm	Difference. Within the range. It does not introduce any new concerns for safety or efficacy which has been confirmed performance testing.

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Working length	1200mm, 1800mm, 2000mm, 2300mm, 2700mm.	1800mm, 2000mm, 2300mm.	Difference. More specifications. It does not introduce any new concerns for safety or efficacy which has been confirmed performance testing.
Patient-contact potential (Duration and type of contact)	Externally communicating medical devices in contact with tissue. The contact duration is limited exposure (i.e. contact is up to 24 hours).	Externally communicating medical devices in contact with tissue. The contact duration is limited exposure (i.e. contact is up to 24 hours).	No difference
Sterility (SAL of 10^{-6})	Yes	Yes	No difference
Sterilization method	Ethylene Oxide	Ethylene Oxide	No difference
Biocompatibility	ISO 10993-4:2017, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-11:2017, ISO 10993-23:2021, USP <151>, 2017	Comply with ISO 10993 standards	The biocompatibility testing for subject device has been tested in accordance with the ISO 10993-1: 2018, and results are qualified.

8. Nonclinical test *[21 CFR 807.92 (b) (1)]*

Performance testing was conducted on the following items to support the marketing claims and to confirm that the safety and effectiveness of the subject device is at least equivalent to the predicate device.

- Appearance
- Cleanliness
- Leakage
- Puncture force
- Stiffness
- Resistance of needle tube to breakage
- Corrosion resistance of needle tube
- Particle contamination
- Flexible properties
- Flow
- Compatibility and performance with endoscopes
- Luer lock hub
- Etc.

The EO residual and ECH residual were measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014 and AAMI/ANSI/ISO 10993-7:2008(R)2012.
The shelf-life for three years had been validated in accelerated testing according to ASTM F1980-16 (2016) and the requirements on packaging for terminally sterilized medical device per ISO 11607-1 and ISO 11607-2 are also met. The testing successfully demonstrated essential performance is achieved before and after the shelf life test.
Biocompatibility was tested by the third GLP laboratory following ISO 10993-1:2018;

9. Clinical test *[21 CFR 807.92 (b) (2)]*

No clinical test is included in this submission.

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10. Conclusion ***[21 CFR 807.92 (b) (3)]***
Based on the information provided within this 510(k) submission, the subject device is substantially equivalent to the predicate device and is as safe, as effective and performs as well as the legally marketed predicate device.