December 2, 2025

Changzhou New Med Micro-Medtech Co., Ltd.
℅ Kyra Kang
Official Correspondent
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room1308, Baohua International Plaza,
West Guangzhong Road 555, Jingan District
Shanghai, China

Re: K252021
Trade/Device Name: Disposable Endoscopic Injection Needles
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FBK
Dated: October 27, 2025
Received: October 27, 2025

Dear Kyra Kang:

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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252021

Device Name

Disposable Endoscopic Injection Needles

Indications for Use *(Describe)*

This product is intended to be used in conjunction with an endoscope for the submucosal injection in the digestive 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I. Submitter

Changzhou New Med Micro-Medtech Co., Ltd.
No. 99 of Longxi Avenue, Zhulin Town, Jintan District, Changzhou City, Jiangsu Province, China
Contact person: Ashe Chen
Position: manager
Tel.: 86-18352577510
E-mail: ashe.chen@newmed-medical.com

Preparation date: March 18, 2025

Submission Correspondent
Ms. Kyra Kang
Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	Disposable Endoscopic Injection Needles
Common name:	Endoscope and accessories
Regulation Number:	21 CFR 876.1500
Regulatory Class:	Class II
Product code:	FBK
Review Panel:	Gastroenterology/Urology

III. Predicate Devices

510(k) Number:	K213914
Trade name:	Injection Needle
Common name:	Endoscope and accessories
Classification:	Class II
Product Code:	FBK
Manufacturer	Jiangsu Vedkang Medical Science and Technology Co.,Ltd.

IV. Device description

The Disposable Endoscopic Injection Needle is intended to be used in conjunction with an endoscope for the submucosal injection in the digestive tract.

This device consists of the handle assembly, inner and outer tubes, introducer, and needle tip assembly.

The proposed devices are sterilized by Ethylene Oxide Gas to achieve a SAL of 10-6 and supplied sterility maintenance package which could maintain the sterility of the device during the shelf life of 3 years.

V. Indication for use

This product is intended to be used in conjunction with an endoscope for the submucosal injection in the digestive tract.

VI. Comparison of technological characteristics with the predicate devices

Table 1 General Comparison of Disposable Endoscopic Injection Needles

Characteristics	Proposed device	Predicate device (K213914)	Discussion
Product	Disposable Endoscopic Injection Needles	Injection Needle	/
Product Code	FBK	FBK	Same
Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
Class	Class II	Class II	Same
Indication for Use	This product is intended to be used in conjunction with an endoscope for the submucosal injection in the digestive tract.	The device is intended to be used with an endoscope to perform endoscopic vascular or submucosal injection in the GI tract.	Similar
Configuration	handle assembly, inner and outer tubes, introducer, and needle tip	needle, connector tube, guiding head, inner tube, outer tube, protective sleeve, front handle, injection handle, front handle cover, boosting tube	Similar
Environment of use	Hospital	Hospital	Same
Intended users	The device must be used by trained doctors or technicians	The device must be used by trained doctors or technicians	Same
Single Use	Single Use	Single Use	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Working Length	1200mm,1600mm, 1800mm, 2300mm	1200mm,1800mm,2300mm, 3000mm	Similar

Minimum working channel	2.0mm, 2.8mm	2.0mm, 2.8mm	Same
Needle Size	21G, 23G, 25G	19G, 20G, 21G, 22G, 23G, 25G	Same (covered by Predicate device)
Needle Length	3mm, 4mm, 5mm, 6mm	3mm, 4mm, 5mm, 6mm, 8mm	Same (covered by Predicate device)
Patient contact material	Needle tip:06Cr19Ni10 Introducer:06Cr19Ni10 Inner tube:PTFE Outer Tube: PTFE Handle Assembly: ABS	Needle: S30400 Guiding Head: S30300 Inner Tube: PTFE or PP Outer Tube: PTFE or PP Injection Handle: ABS Boosting Tube: S30400	Similar
Biocompatibility	Comply with the ISO 10993 Standards	Comply with the ISO 10993 Standards	Same
Sterilization Method	EO Sterilized	EO Sterilized	Same
SAL	10-6	10-6	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

VII. Non-Clinical Testing

The device described in this summary was tested and demonstrated to be in conformance with the following standards:

ISO 10993-4:2017
ISO 10993-5:2009
ISO 10993-7:2008
ISO 10993-10:2021
ISO 10993-11:2017
ISO 10993-23:2021
ASTM F1980-16
ASTM F88/88M-15
ASTM F1929-15
ASTM F1886-16
USP <85> Bacterial Endotoxins Test

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.