August 25, 2026

Promisemed Hangzhou Meditech Co., Ltd.
Zearou Yang
Regulatory Affairs Manager
#1388 Cangxing St., Cangqian Community, Yuhang District
Hangzhou, 311121
China

Re: K261719
Trade/Device Name: Promisemed X-Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 13, 2026
Received: August 13, 2026

Dear Zearou Yang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

SHRUTI N. MISTRY -S

Shruti Mistry
Assistant Director
DHT3C: Division of Drug Delivery and General Hospital Devices, and Human Factors
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261719

Please provide the device trade name(s).

Promisemed X-Safety Pen Needle

Please provide your Indications for Use below.

Promisemed X-safety pen needle is intended for use with needle based injector for the injection of drugs.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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

K261719-510(k) Summary

Date prepared: 2026-08-21

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
Phone	+86 571 88772985
Email	zearou.yang@promisemed.ca
2. Device *[21 CFR 807.92 (a) (2)]*	
Name	Promisemed X-Safety Pen Needle
Common Name	X-Safety Pen Needle
Classification Name	Hypodermic Single Lumen Needle
Regulation Number	21 CFR 880.5570
Class	Class II
Product Code	FMI
3. Legally Marketed Predicate Device *[21 CFR 807.92 (a) (3)]*	
Predicate Name	Promisemed X-Safety Pen Needle
510(k) Number	K220129
Product Code	FMI
Reference Devices	No reference devices were used in this submission.

4. Device Description *[21 CFR 807.92 (a) (4)]*

Promisemed X-Safety Pen Needle is a single-use, double-ended, sterile needle for needle-based injection systems (NISs) that fulfill the specifications of ISO 11608-1. This device is constructed as a double-ended, stainless-steel needle of various sizes that is with a threaded plastic hub. The device includes needle shielding safety features (at both patient-end and cartridge-end or at patient-end only) to reduce the risk of needle stick injury and its container can be provided as short or long type. It is packaged in a sealed sterility barrier, and the needle is lubricated. This is a single-use device and delivered sterile. Sterilization process is validated according to EN ISO 11135. Sterilization process undergoes routine control.

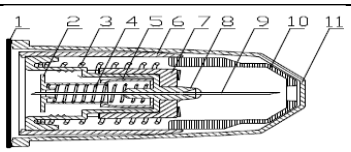
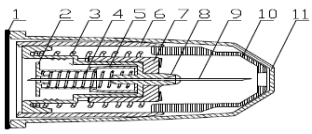
5. Indication for use *[21 CFR 807.92 (a) (5)]*

Promisemed X-safety pen needle is intended for use with needle based injector for the injection of drugs.

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

The subject device has the same technological characteristics (design, material, chemical composition, principle of

operation, etc.) as the predicate device. The safety feature is passive, same as predicate device. Size and shape of container is same as predicate device. The differences between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. We concluded the subject device is substantially equivalent to the identified predicate device.

<table>
<tr><th>Item of description</th><th>Predicate device
(K220129)</th><th>Subject device
(K262719)</th><th>Similar/ Difference</th><th>Safety / Effectiveness Statement</th></tr>
<tr><td>Common name</td><td>X-Safety Pen Needle</td><td>X-Safety Pen Needle</td><td>N/A</td><td>/</td></tr>
<tr><td>Manufacturer</td><td>Promisemed Hangzhou Meditech Co., Ltd.</td><td>Promisemed Hangzhou Meditech Co., Ltd.</td><td>Same</td><td>All produced by the same manufacturer.</td></tr>
<tr><td>Intended use /Indications</td><td>Promisemed X-safety pen needle is intended for use with needle-based injector for the injection of drugs.</td><td>Promisemed X-safety pen needle is intended for use with needle-based injector for the injection of drugs.</td><td>Same</td><td>No new concerns</td></tr>
<tr><td>Target population</td><td>General use</td><td>General use</td><td>Same</td><td>No new concerns</td></tr>
<tr><td>Anatomical site</td><td>Subcutaneous tissue</td><td>Subcutaneous tissue</td><td>Same</td><td>No new concerns</td></tr>
<tr><td>Where used</td><td>Home Environment, Professional Healthcare Facility</td><td>Home Environment, Professional Healthcare Facility</td><td>Same</td><td>No new concerns</td></tr>
<tr><td>Intended users</td><td>Lay person, Healthcare professional users</td><td>Lay person, Healthcare professional users</td><td>Same</td><td>No new concerns</td></tr>
<tr><td>Structure</td><td> 
Example of representative type A</td><td> 
Example of representative type A</td><td>Same</td><td>No new concerns.</td></tr>
<tr><td>Materials (tissue-contacting)</td><td><table><tr><th>Components</th><th>Material</th><th>Contact type</th></tr><tr><td>Needle tube</td><td>X5CrNi18-10</td><td>Direct contact with tissue</td></tr><tr><td>Trigger</td><td>Acrylonitrile Butadiene Styrene (ABS)</td><td>Intact skin</td></tr><tr><td>Container</td><td>Polypropylene (PP)</td><td>Intact skin</td></tr></table></td><td><table><tr><th>Components</th><th>Material</th><th>Contact type</th></tr><tr><td>Needle tube</td><td>X5CrNi18-10</td><td>Direct contact with tissue</td></tr><tr><td>Trigger</td><td>Acrylonitrile Butadiene Styrene (ABS)</td><td>Intact skin</td></tr><tr><td>Container</td><td>Polypropylene (PP)</td><td>Intact skin</td></tr></table></td><td>Same</td><td>No new concerns.</td></tr>
<tr><td>Needle gauge</td><td>29G, 30G, 31G, 32G.</td><td>29G, 30G, 31G, 32G.</td><td>Same</td><td>No new concerns.</td></tr>
<tr><td>Needle length</td><td>4mm, 5mm, 6mm, 8mm</td><td>4mm, 5mm, 6mm, 7mm, 8mm.</td><td>Difference</td><td>No new concerns. Subject device has additional needle length (7mm) than predicate device for clinical selection. It does not introduce new risks about effectiveness and safety because that the technical characteristic and operation method is same with the predicate device.</td></tr>
<tr><td>Sterilization method</td><td>EO sterilization</td><td>EO sterilization</td><td>Same</td><td>No new concerns</td></tr>
<tr><td>Sterility</td><td>SAL of 10^{-6}</td><td>SAL of 10^{-6}</td><td>Same</td><td>No new concerns</td></tr>
<tr><td>Single use</td><td>Yes</td><td>Yes</td><td>Same</td><td>No new concerns</td></tr>
</table>

Biocompatibility	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity; - Skin Irritation: No evidence of skin irritation; - Skin Sensitization: No evidence of sensitization; - Acute Systemic Toxicity: No systemic toxicity; - Hemolysis: No evidence of hemolysis; - Pyrogen: Non pyrogenic;	Complied with ISO10993 series standards, and the following tests are performed - Cytotoxicity: No cytotoxicity; - Skin Irritation: No evidence of skin irritation; - Skin Sensitization: No evidence of sensitization; - Acute Systemic Toxicity: No systemic toxicity; - Hemolysis: No evidence of hemolysis; - Pyrogen: Non pyrogenic;	Same	No new concerns
Standards met	Complied with ISO 7864, ISO 9626, ISO 11608-2;	Complied with ISO 7864, ISO 9626, ISO 11608-2;	Same	No new concerns
Compatibility with other devices	It is in conjunction with needle-based injection systems (e.g. pen injectors).	It is in conjunction with needle-based injection systems (e.g. pen injectors).	Same	No new concerns
Compatibility with the environment	No specific requirements.	No specific requirements.	Same	No new concerns
Energy used and/or delivered	None.	None.	Same	No new concerns
Electrical safety	N/A.	N/A.	/	/
Mechanical safety	N/A.	N/A.	/	/
Chemical safety	N/A.	N/A.	/	/
Thermal safety	N/A.	N/A.	/	/
Radiation safety	N/A.	N/A.	/	/

The following changes were identified between the subject and predicate devices:

- Added needle length (7mm): Subject device has additional needle length (7mm) than predicate device for clinical selection. It does not introduce new risks about effectiveness and safety because the technical characteristics and operation method are the same as the predicate device.

The subject device has the same intended use and technological characteristics as the predicate device. The basic technological and operating principles are the same for both devices. Both the subject and predicate devices are disposable, sterile, single patient use devices. As evidenced by comparison table above, the subject device is substantially equivalent to the predicate device.

7. Non-Clinical and/or Clinical Tests Summary & Conclusions *[21 CFR 807.92 (b) (1)]*

The subject device meets all the requirements for overall design and performance. Performance testing confirms that the output meets the design inputs and specifications. Internal verification and validation testing confirms that product specifications are met, which support the intended use and technological characteristics as compared to the predicate devices. The information supports the substantial equivalence to the referenced predicate device.

Test items		Standard reference
Physical performance	Needle tubing materials	ISO 9626:2016, clause 4
	Surface finish	ISO 9626:2016, clause 5.2
	Cleanliness	ISO 9626:2016, clause 5.2
	Stiffness	ISO 9626:2016, clause 5.8
	Resistance to breakage	ISO 9626:2016, clause 5.9
	Resistance to corrosion	ISO 9626:2016, clause 5.10
	Penetration force	ISO 7864:2016, Annex D
	Dimensions	ISO 9626:2016, clause 5.5 to 5.6; ISO 11608-2:2022, clause 5.2.3

	Flow rate through the needle	ISO 11608-2:2022, clause 5.2.6.1
	Bond between hub and needle tube	ISO 11608-2:2022, clause 5.2.7
	Needle points	ISO 11608-2:2022, clause 5.2.4
	Freedom from defects	ISO 11608-2:2022, clause 5.2.5
	Lubrication	ISO 11608-2:2022, clause 5.2.5
	Dislocation of patient end	ISO 11608-2:2022, clause 5.2.8
	Needle container embedding force	ISO 11608-2:2022, clause 5.3
	Ease of assembly	ISO 11608-2:2022, clause 5.2.9 and 5.3.3
	Functional compatibility with NISs	ISO 11608-2:2022, clause 5.3
	Ease of disassembly	ISO 11608-2:2022, clause 5.2.9 and 5.3.3
	Needle container embedding force	Internal requirement JCQ-Q-146
	Accidental access to a sharp once in safe mode	ISO 23908:2024, clause 5.1.5
	Safety mechanism activation	ISO 23908:2024, clause 6
	Safety overriding and unlocking force after activation	ISO 23908:2024, clause 6
Biological performance	Sterility	USP <71>
	Bacterial endotoxin	USP <161>
Chemical performance	Limits for acidity and alkalinity	ISO 9626:2016, clause 5.4
	Total content of heavy metals	ISO 7864:2016, clause 4.5
	Residual ethylene oxide	ISO 10993-7:2026, clause 4.3.2
Packaging performance	Packaging appearance	ISO 11608-2:2022, clause 10
	Seal strength	ISO 11607-1:2019
	Penetration test	ISO 11607-1:2019

8. Conclusion *[21 CFR 807.92 (b) (3)]*

Based on the nonclinical performance testing described above, the Promisemed X-Safety Pen Needle (subject device) has been demonstrated to be substantially equivalent to the predicate device (K220129). The subject device has the same intended use as the predicate device. While certain technological differences exist (needle length), these differences do not raise different questions of safety and effectiveness when compared to the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.