March 14, 2025

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

Re: K243332
Trade/Device Name: Promisemed Safety Huber Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: PTI
Dated: December 23, 2024
Received: February 12, 2025

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 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,

for Rong Guo -S Digitally signed by Rong Guo -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

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)*

K243332

Device Name

Promisemed Safety Huber Needles

Indications for Use *(Describe)*

The needle is used to access surgically implanted vascular ports.
Safety Huber Needles is a standard non coring intravascular infusion set with a non-coring Huber type right angle needle and a manually activated needle stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by sheathing the needle. This device is for adult use only.
In addition, when used with ports that are indicated for power injection of contrast media into the central venous system, the high pressure resistant model is indicated for high-pressure injection of contrast media for CT imaging.

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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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: 2025-03-14

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
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Email	zearou.yang@promisemed.ca
2. Device *[21 CFR 807.92 (a) (2)]*	
Name	Promisemed Safety Huber Needles
Common Name	Safety Huber Needles
Classification Name	Needle, Hypodermic, Single Lumen
Regulation Number	880.5570
Class	Class II
Product Code	PTI
3. Legally Marketed Predicate Device *[21 CFR 807.92 (a) (3)]*	
Predicate Name	Safety Huber Needles
510(k) Number	K230715
Product Code	PTI
Reference Devices	No reference devices were used in this submission.

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

Safety Huber Needle is a standard non-coring intravascular infusion set with a non-coring Huber type right angle needle and a manually activated needle-stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by sheathing the needle.

The device includes an integrated extension set consisting of a Huber needle and safety mechanism (Type B, Type D and Type E), needle infusion tubing (pressure resistance or non-pressure resistance), Y-injection site, clamp and female Luer lock adapter. The pressure resistance tubing can be used for power injection up to 330 psi. The device will be retained on patient for 24h to 7 days.

This submission is new design primarily involve changes to the type C name, the addition of new needle lengths and new type E.

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

The needle is used to access surgically implanted vascular ports.

Safety Huber Needles is a standard non coring intravascular infusion set with a non-coring Huber type right angle needle and a manually activated needle stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by sheathing the needle. This device is for adult use only.

In addition, when used with ports that are indicated for power injection of contrast media into the central venous system, the high pressure resistant model is indicated for high-pressure injection of contrast media for CT imaging.

6. Indications for Use Comparison *[21 CFR 807.92 (a) (5)]*

No difference.

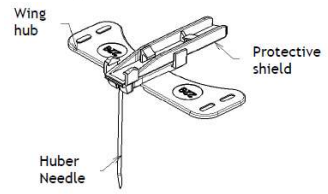
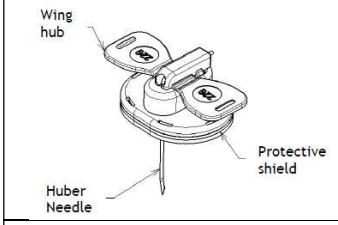
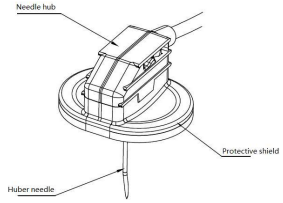
7. Comparison of Technological Characteristic *[21 CFR 807.92 (a) (6)]*

The subject device has the same intended use and technological characteristics as the predicate device. The similarities above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness or safety of the subject device when compared to the predicate device. The subject device is substantially equivalent to the identified predicate device.

At a high level, the subject and predicate devices are based on the following same technological elements:

Item of description	Cleared device (K230715)	Modified device	Comments on Similarities/ Differences	Safety/ Effectiveness Statement
Common name	Safety Huber Needles	No change	N/A	No new concerns. The common name remains unchanged, ensuring consistency with the intended use.
Classification name	Needle, Hypodermic, Single Lumen (21 CFR 880.5570)	No change	N/A	No new concerns. The classification name remains consistent.
Device class	Class II	No change	N/A	No new concerns. The device remains in Class II, indicating no change in risk level.
Product Code	PTI	No change	N/A	No new concerns. The product code remains the same, reflecting no change in device functionality.
General description	Safety Huber Needle is a standard non-coring intravascular infusion set with a non-coring Huber type right angle needle and a manually activated needle-stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by sheathing the needle. The device includes an integrated extension set consisting of a Huber needle and safety mechanism (Type B and Type C), needle infusion tubing (pressure resistance or non-pressure resistance), Y-injection site, clamp and female Luer lock adapter. The pressure resistance tubing can be used for power injection up to 330 psi. The device will be retained on	Safety Huber Needle is a standard non-coring intravascular infusion set with a non-coring Huber type right angle needle and a manually activated needle-stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by sheathing the needle. The device includes an integrated extension set consisting of a Huber needle and safety mechanism (Type B, Type D and Type E), needle infusion tubing (pressure resistance or non-pressure resistance), Y-injection site, clamp and female Luer lock adapter. The pressure resistance tubing can be used for power injection up to 330 psi. The	Name of Type C is changed to Type D. Type E was added.	No new concerns. The change to type name and a broader type do not introduce new risks as the fundamental technology and operation remain the same.

	patient for 24h to 7 days.	device will be retained on patient for 24h to 7 days.		
Principle of operation	Type B and Type C: The Safety Huber Needle is for insertion into the septum of a subcutaneously implanted port and for the infusion of fluids into the port. It is designed with flexible wings which allow the user to securely hold the device for insertion and removal of the needle. The protective base and protective shield are made of clear plastic that allow the user to visualize placement of the needle. A foam pad is present on the patient-contacting side of the protective base. The device include a safety design allowing the safety shield covers the needle tip after usage.	Type B and Type D: No change	Name of Type C is changed to Type D.	No new concerns. The principles of operation remain unchanged, ensuring consistent performance.
	/	Type E: Same as Type D	Type E was added.	
Indication of use	The needle is used to access surgically implanted vascular ports. Safety Huber Needles is a standard non coring intravascular infusion set with a non-coring Huber type right angle needle and a manually activated needle stick prevention safety mechanism which reduces the risk of accidental needlestick injuries by sheathing the needle. This device is for adult use only. In addition, when used with ports that are indicated for power injection of contrast media into the central venous system, the high pressure resistant model is indicated for high-pressure injection of contrast media for CT imaging.	No change.	N/A	No new concerns. The change to type name and a broader type do not introduce new risks as the fundamental technology and operation remain the same.
Type	Type B, Type C	Type B, Type D and Type E	Name of Type C is changed to Type D. Type E was added.	No new concerns. The change to type name and a broader type do not introduce new risks as the fundamental technology and operation remain the same.
Needle size	19G, 20G, 22G	No change	N/A	No new concerns. The needle size remains unchanged.
Needle length	Type B:19mm, 25mm, 38mm	No change	N/A	No new concerns. The needle length remains unchanged.
	Type C:19mm, 25mm, 38mm	Type D: 13mm, 15mm, 19mm, 25mm, 32mm, 38mm	Name of Type C is changed to Type D. New needle length sizes were added for Type D.	No new concerns. The addition of new lengths do not introduce new risks as the fundamental technology and operation remain the same.
	/	Type E: 13mm, 15mm, 19mm, 25mm, 32mm, 38mm	Type E was added.	
Needle bevel design	Non-coring angled needle	No change	N/A	No new concerns. The addition of new lengths and new type do not

<table>
<tr><td></td><td></td><td></td><td></td><td>introduce new risks as the fundamental technology and operation remain the same.</td></tr>
<tr><td>Color</td><td><table><tr><th>Needle gauge</th><th>Color</th></tr><tr><td>19G</td><td>Cream</td></tr><tr><td>20G</td><td>Yellow</td></tr><tr><td>22G</td><td>Black</td></tr></table></td><td>Type B, Type D and Type E: No change;</td><td>Color designation system is remained no change.
The color for Type E is indicated on the clamp.</td><td>No new concerns. The addition of new lengths and new type do not introduce new color system requirement as met with ISO 6009.</td></tr>
<tr><td rowspan="3">Schematic diagram (safety mechanism)</td><td>Type B:
 
</td><td>No change</td><td rowspan="3">Name of Type C is changed to Type D.
Type E was added.
The difference of Type E and Type D is only the shape of hub which Type E is without wing.</td><td rowspan="3">No new concerns. The addition of new type do not introduce new risks as the fundamental technology and operation remain the same.</td></tr>
<tr><td>Type C:
 
</td><td>No change</td></tr>
<tr><td>/</td><td>Type E:
 
</td></tr>
<tr><td>Material</td><td>Type B, Type C</td><td>Type B, Type D: No change
Type E added.</td><td>Name of Type C is changed to Type D.
Type E is without wing and other component material is same with type D.</td><td>No new concerns. Type E is without wing and other material is same with type D and does not affect safety.</td></tr>
<tr><td>Performance requirements</td><td>Remain no change</td><td>No change</td><td>N/A</td><td>No new concerns. Performance requirements remained unchanged, ensuring consistent functionality.</td></tr>
<tr><td>Labeling</td><td>Remain no change</td><td>Type B, Type D and Type E</td><td>Name of Type C is changed to Type D.
Type E was added.</td><td>No new concerns. Labeling updates meet current standards and enhance the device's safety and usability.</td></tr>
</table>

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

To support substantial equivalence to the predicate device, Promisemed Hangzhou Meditech Co., Ltd. completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met.
Verification and Validation Activities - Design Changes:

- Name and labeling: Visual inspections were conducted on unit packaging to ensure metric size labeling compliance with ISO 7864.
- Needle length (type D): The needle's dimensions, including outer diameter and length, were measured, and found to comply with drawing requirements.
- Performance test (type E): Full performance was tested, including appearance, dimension, safety mechanism, etc. and found to comply with ISO 7864, ISO 9626, ASTM F3212-16 and ISO 23908.

All verification and validation tests passed without deviations, confirming that the subjective device meet the necessary design specifications and regulatory requirements. The tests demonstrated that the product modifications did not introduce any new risks related to safety or effectiveness when compared to the predicate device.

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

No clinical test is included in this submission.

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.