June 4, 2025

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

Re: K250961
Trade/Device Name: Blood collection tube holders
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: March 28, 2025
Received: March 31, 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 and Part 809); 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,

David Wolloscheck -S

David Wolloscheck, Ph.D.
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.

510(k) Number *(if known)*
K250961

Device Name
Blood collection tube holders

Indications for Use *(Describe)*
It is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections of venous blood. It is for adult use only.

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.

K250961-510(k) Summary

Date prepared: 2025-06-02

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
Fax	86 571 88772985
Email	zearou.yang@promisemed.ca
2. Device *[21 CFR 807.92 (a) (2)]*	
Name	Blood collection tube holders
Common Name	Blood Collection Tubes, Vials, Systems, Serum Separators
Classification Name	Blood Specimen Collection Device
Regulation Number	862.1675
Class	Class II
Product Code	JKA
3. Legally Marketed Predicate Device *[21 CFR 807.92 (a) (3)]*	
Predicate Name	Luer Adapter with Holder
510(k) Number	K230080
Product Code	JKA
Reference Devices	No reference devices were used in this submission.

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

Blood collection tube holders is single use and sterile, it is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections of venous blood. It is sterile and to be used for assisting blood collection. The device consists of a puncture needle hub, puncture needle, rubber boot and holder. It is packaged in a sealed sterility barrier. This is a single-use device and delivered sterile. Sterilization process is validated according to EN ISO 11135. Shelf life is 5 years.

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

It is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections of venous blood. It is for adult use only.

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

Other than the difference in the name of predicate product, there are no differences in the indications for use of the subject device when compared to the predicate device.

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

Blood collection tube holders is substantially equivalent to the predicate device, Luer Adapter with Holder, K230080 in that these devices have same intended use and technological characteristics. 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. The differences between the subject device and predicate device do not affect the basic design principle, usage of the subject device.

Items	Subject Device	Predicate Device (K230080)	Comments
Trade Name	Blood collection tube holders	Luer Adapter with Holder	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	Yangzhou Medline Industry Co., Ltd.	
Intended use environment	Regular medical institutions	Regular medical institutions	Same
User	These devices are to be used by properly trained healthcare professionals only in accordance with instructions.	These devices are to be used by properly trained healthcare professionals only in accordance with instructions.	Same
Patient population	It is used for adult patients who need to withdrawal of blood samples.	It is used for patients who need to withdrawal of blood samples.	Same
Dimensions	needle guage:20G OD(mm):0.89-0.91; ID(mm):0.66±0.02; Effective length(mm): 14.5±1 holder length:53.3mm	Needle guage:21G,22G,23G,25G length:5/8", 3/4", 1/2", 1", 11/4", 11/2"	Analysis 1
Components	The device mainly consists of puncture needle hub, puncture needle, rubber boot and holder.	The devices are composed of Needle cap, Needle cannula, Safety sheath, Needle hub, Luer adapter and Holder.	Analysis 2
Operating Principle	Blood collection tube holders is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections of venous blood. The Pre-attached Holder is designed to aid in protection against accidental non-patient needle injury and blood splatter. It is provided sterile and single use. The proposed devices are composed of puncture needle hub, puncture needle, rubber boot and holder.	The Luer adapter with Holder is intended to be used with vein puncture needle and vacuum blood collection tube for multiple collections of venous blood. The Pre-attached Holder is designed to aid in protection against accidental non-patient needle injury and blood splatter. It is provided sterile and single use. The proposed devices are composed of Needle cap, Needle cannula, Safety sheath, Needle hub, Luer adapter and Holder.	Same
Reuse durability	Single Use	Single Use	Same
Materials	- puncture needle hub (AHA-02/BTH-01): Acrylonitrile Butadiene Styrene (ABS) - puncture needle hub (AHA-01/AHA-03): Polypropylene (PP) - puncture needle: Stainless Steel (06Cr19Ni10) - Rubber boot: Polyisoprene rubber - Holder: Polypropylene (PP)	- Connect base: ABS - Non-patient end needle tube: Stainless Steel SUS304 - Rubber sleeve: Gather Isoprene Rubber - Needle Holder (PP)	Complied with ISO 10993 series standards

Performance	Complied with ISO 7864, ISO 9626, ISO 80369-7	Complied with ISO 7864, ISO 9626, ISO 80369-7	Same
Sterilization method	EO Sterilization	EO Sterilization	Same

Analysis 1- Dimensions

The subject device has different dimensions from predicate device. The subject device scope of dimension is within the scope of predicate device. The subject devices were tested according to ISO 7864:2016 and ISO 9626:2016 standards, and the results met the requirements of the standards. Therefore, this difference does not raise new or different questions of safety and effectiveness.

Analysis 2- Components

The components and configuration between subject device and predicate device is similar, and it's only a difference in the textual description of the component. Therefore, this difference does not raise new or different questions of safety and effectiveness.

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.

- Puncture force
- Stiffness
- Resistance to breakage
- Resistance to corrosion
- Bond between hub and needle tube
- Tensile strength
- Rubber leakage test
- Characteristics of Adapter

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 five 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.

The subject device is categorized as externally communicating medical device (blood path, indirect) and limited exposure (A) per ISO 10093-1:2018. Each biocompatibility endpoint was assessed, e.g. cytotoxicity, sensitization, irritation, acute systemic & pyrogenicity and hemocompatibility.

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 these 510(k) submissions, the subject device is substantially equivalent to the predicate device and is as safe, and effective as the legally marketed predicate device.