June 25, 2021

Promisemed Hangzhou Meditech Co., Ltd.
% John Beasley
Official Correspondent
MedTech Review, LLC
257 Garnet Garden Street
Henderson, Nevada 89015

Re: K211293
Trade/Device Name: Safety Winged Blood Collection Sets
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI, FPA
Dated: April 16, 2021
Received: April 26, 2021

Dear John Beasley:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Payal Patel
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K211293

Device Name

Safety Winged Blood Collection Set - Needle Diameter (21, 23, 25 Guage) - Tube Length (10, 19, 30 cm) - HOLDER, SBC-xxxxH;
Safety Winged Blood Collection Set - Needle Diameter (21, 23, 25 Guage) - Tube Length (10, 19, 30 cm) - ADAPTER, SBC-xxxxA;
Safety Winged Blood Collection Set - Needle Diameter (21, 23, 25 Guage) - Tube Length (10, 19, 30 cm) - W/O Puncture, SBC-

Indications for Use *(Describe)*

The safety winged blood collection set is single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adaper and/or tube holder. The device is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Promisemed Hangzhou Meditech Co., Ltd.

No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China.

510(k) Summary

Updated: 06/18/2021

Contact Details	21 CFR 807.92(a)(1)
Applicant Name	Promisemed Hangzhou Meditech Co., Ltd.
Applicant Address	No. 12, Longtan Road, Cangqian Street, Yuhang District, Hangzhou City, Zhejiang, 311121, CH
Applicant Telephone Number	865-718-8772985
Applicant Contact	Mr. Zearou Yang
Applicant Contact Email	zearou.yang@promisemed.ca
Correspondent Name	MedTech Review, LLC
Correspondent Address	257 Garnet Garden Street, Henderson, NV, 89015, US
Correspondent Telephone Number	1-612-889-5168
Correspondent Contact	Mr. John Beasley, RAC (US)
Correspondent Contact Email	john@medtechreview.com

Device Name	21 CFR 807.92(a)(2)
Device Trade Name	Safety Winged Blood Collection Sets
Common Name	Safety Blood Collection Device for Single Use
Classification Name	NEEDLE, HYPODERMIC, SINGLE LUMEN
Regulation Number	880.5570
Product Code	FMI/FPA

Legally Marketed Predicate Devices		21 CFR 807.92(a)(3)
Predicate [510(k)] #	Predicate Trade Name	Product Code
K170276	Gemtier Medical (Shanghai) Inc. Safety Blood Collection Device for Single Use	FMI/FPA

Device Description Summary	21 CFR 807.92(a)(4)

The Promisemed Safety Blood Collection sets are single-use, sterile, venipuncture needles used for blood collection or short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

Intended Use/Indications for Use	21 CFR 807.92(a)(5)

The safety winged blood collection set is single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adapter and/or tube holder. The device is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.

Indications for Use Comparison	21 CFR 807.92(a)(5)
Other than the difference in the name of the device and the fact that they are all connected to flexible tubing (these are sets), there are no differences in the indications for use of the subject device when compared to the predicate device.	
Technological Comparison	**21 CFR 807.92(a)(6)**
Compared with the predicate device, the subject device is identical in mechanism of action, materials, needle point, sterilization method, and biocompatibility. The subject device has the same performance specifications except for needle length. Through performance bench testing, the subject device and the predicate device demonstrated to be substantially equivalent.	

Specification	Predicate Device	Subject Device	Discussion of Differences
Device name	Safety Blood Collection Device for Single Use	Safety Winged Blood Collection Sets	The subject device brings attention to the “wings” in the device name, as well as properly defines the device as a “set”. The differences do not introduce any new concerns for safety or efficacy.
K number	K170276	K211293	-
Product code and classification name	FMI, Needle, Hypodermic, Single Lumen	FMI, Needle Hypodermic, Single Lumen	No difference
Indications for use	The SAFETY BLOOD COLLECTION DEVICE FOR SINGLE USE is a single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adapter and/or tube holder. The SAFETY BLOOD COLLECTION DEVICE FOR SINGLE USE is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The venipuncture needle is designed to	The safety winged blood collection set is single-use, sterile, winged venipuncture needle bonded to a flexible tubing with or without a luer adapter and/or tube holder. The device is used for blood collection and/or the short-term infusion of intravenous fluids (up to 2 hours under direct clinical supervision). The blood-collection needle is designed to be covered with a safety mechanism, which can be activated to cover	Difference in the name of the device and the fact that they are all connected to flexible tubing (these are sets). The differences do not introduce any new concerns for safety or efficacy.

Specification	Predicate Device	Subject Device	Discussion of Differences
	be covered with a safety mechanism, which can be activated to cover needle immediately following venipuncture to aid in the protection against accidental needlestick injury.	the needle immediately following venipuncture to aid in the protection against accidental needlestick injury.	
Indicated for infusion	Yes	Yes	No difference
Single use	Yes	Yes	No difference
Mechanism of safety blood collection	Latch mechanism: press both sides of the safety mechanism to release the lock first and then slide the safety mechanism to activate.	Latch mechanism: Place the index finger on the curved design to press gently, hold the two wings by the thumb finger and middle finger and withdraw the wings back to activate the safety mechanism until hearing sound of CLICK. The click is a sign that the Safety mechanism has been correctly activated	The subject device requires use of one finger to press the release and incorporates the wings for activating the safety mechanism. The differences do not introduce any new concerns for safety or efficacy.
Materials:			
Venipuncture Needle	Stainless Steel	Stainless Steel	No difference
Tubing	PVC	PVC	No difference
Wing	PVC	PVC	No difference
Sleeve	PE	ABS	No difference
Retractable Cartridge	PE	PE	No difference
Luer adapter	PP	PVC	No difference
Tube Holder	PP	ABS	No difference
Blood collection needle protector	PP	PE	No difference
Rubber cover	Synthetic Rubber	Nitrile Rubber	Predicate device unspecified. The use of nitrile rubber does not introduce any new concerns for safety or efficacy.

Specification	Predicate Device	Subject Device	Discussion of Differences
Components:			
Tubing, Wing, Luer connectors	Yes	Yes	No difference
Plastic sleeve, venipuncture needle stand	Yes	Yes	No difference
Luer adapter, tube holder, blood collection needle, protection mechanism	Yes	Yes	No difference
Performance:			
Needle Gauge Sizes	21G, 23G, 25G	21G, 23G, 25G	No difference
Tubing Length	10 cm to 35 cm	10 cm, 19cm, 30 cm	No difference
Needle Length	20mm	19mm	The needle length of the subject device is shorter in length (19mm) as compared to the predicate device (20mm). The short needle length allows the phlebotomist to insert it at a shallow angle that can increase the ease of use and therefore, does not introduce any new concerns for safety or efficacy.
Needle Point	3-bevel	3-bevel	No difference
Sterile	Ethylene Oxide	Ethylene Oxide	No difference
Non-pyrogen	Yes	Yes	No difference
Shelf life	3 years	3 years	No difference
Biocompatibility	Cytotoxicity, Skin Sensitization, Irritation, Acute Systemic Toxicity, Hemolysis, Pyrogenicity, Bacterial Endotoxins testing have passing results	Cytotoxicity, Skin Sensitization, Irritation, Acute Systemic Toxicity, Hemolysis, Pyrogenicity, Bacterial Endotoxins testing have passing results	No difference

Promisemed®

Promisemed Hangzhou Meditech Co., Ltd.

No. 1388 Cangxing Street, Cangqian Community, Yuhang District,
Hangzhou City, 311121 Zhejiang, China.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Summary:

The needle, tubing, hub, and luer connectors meet the following physical, chemical, biological requirements:

Physical performance	Needle appearance and cleanliness		ISO 7864:2016, clause 4.3
	Needle Size color code		ISO 6009:2016
	Needle Particulate contamination		USP<788>, METHOD 1, Test 1.B
	Bonding strength:	Needle and hub	ISO 7864:2016, clause 4.12
		Tubing and hub	ISO 8536-4:2019, clause 7.3
		Tubing and double wings luer adapter	ISO 8536-4:2019, clause 7.3
	Infusion set leakage		ISO 8536-4:2019, clause 7.2
	Needle patency of lumen		ISO 7864 :2016, clause 4.13, a)
	Dimension	Blood collection needle	ISO 9626 :20 16, clause 5.6, table 1, (TW) ISO 7864 :2016, clause 4.10.2, table1
		Puncturing needle	
	Needle point		ISO 7864:2016, clause 4.11
	Needle Lubrication	Appearance	ISO 7864:2016, clause 4.10.4,
		Quantity	IS0 7886-1:2017, Annex F
	Luer Connector		ISO 80369-7:2016 ISO 80369-20:2015
	Tubing kink stability		ISO 20696:2018, clause 6.7
	Puncture force of needle		ISO 7864:2016, clause 4.11
	Safety protection mechanism		ISO 23908:2011
	Stiffness of needle		ISO 9626 :2016, clause 5.8, table 2 (TW)
	Toughness of needle		ISO 9626:2016, clause 5.9
	Resistance to corrosion of needle		ISO 9626 :2016, clause 5.10
Chemical performance	Reducing matter		ISO 8536-4:2019, clause 8.1
	Metal ions		ISO 8536-4:2019, clause 8.2
	Limits for acidity or alkalinity		ISO 8536-4:2019, clause 8.3
	Residue on evaporation		ISO 8536-4:2019, clause 8.4
	Ethylene oxide residue (EO&ECH)		ISO 10993-7:2008, clause 4.3.4
Biological performance	Bacterial endotoxin		USP <85>
	Sterility		USP <71>
	Pyrogen Test (Rabbit)		USP <151>
	Hemolytic Properties		ASTM F756-17
	Hematology		ISO 10993-4:2017

	Platelet Count Partial Thromboplastin Time	
	Cytotoxicity	ISO 10993-5:2009
	Skin Sensitization Intracutaneous Reactivity	ISO 10993-10:2010
	Acute Systemic Toxicity	ISO 10993-11:2017

Sharps injury protection: Device meets safety mechanism activation requirements as per ISO 23908, internal protocol and test results

Sharps injury protection: Device meets safety overriding/unlocking force after activation requirements as per ISO 23908, internal protocol and test results

Sterilization: A Sterility Assurance Level (SAL) of 10^{-6} has been validated in accordance with the requirements of ISO 11135:2014 for Ethylene Oxide.

Clinical Summary: Not applicable. Substantial equivalence does not depend on clinical test data.

Conclusion:

Based on device comparison information and non-clinical bench testing, the proposed device is substantially equivalent to the legally marketed predicate device (K170276).