November 17, 2021

Promisemed Hangzhou Meditech Co., Ltd.
℅ Wei Shan Hsu
Regulatory manager
Vee Care (Asia) Limited
17th Chung Pont Commercial Building, 300 Hennessy Road
Hong Kong, Hong Kong
China

Re: K211890
Trade/Device Name: Promisemed Sharps container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: MMK
Dated: May 27, 2021
Received: June 21, 2021

Dear Wei Shan Hsu:

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,

For Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211890

Device Name
Promisemed Sharps Container

Indications for Use *(Describe)*
It is intended to be used for health care purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles.

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."

510(k) Summary (K211890)

1 Date Prepared

June 10th , 2021

2 Submitter's Information

Name of Sponsor:

Promisemed Hangzhou Meditech Co., Ltd.

Address:

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

Contact Name:

Zearou Yang

Telephone No.:

+86 571 88772985

Fax No.:

+86 571 88772985

Email Address:

zearou.yang@promisemed.ca

3 Trade Name, Common Name, Classification

Trade/Product Name: Promisemed Sharps Container

Common Name: Sharps container

Classification name: Container, Sharps

Regulation Number: 21 CFR 880.5570

Device Class: Class II

Product Code: MMK

4 Identification of Predicate Device

K190240 Tiger Sharps Containers

5 Description of the Device

The Sharps container is single-use, disposable, non-sterile containers intended to be used for health- care purposes for safe disposal of hazardous sharps such as needles, syringes, lancets and etc. The target population is for qualified personnel in health care facilities and other facilities in which medical sharps may be used.

It is made of injection molded polypropylene plastic, and is composed of base, lid, closure and handle (except pocket collectors). No part of the container is intended to come in contact with patients and the sharps objects that will be placed within the containers.

6 Indication

It is intended to be used for health care purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles.

7 Specification

Model	Capacity (Total)	Capacity (Full line)	Dimensions LxWxH (mm)	Thickness	Empty Weight (grams)	Color
SSC-005L	0.05 L	0.043 L	60 x 27 x 87	Base:1.3-3.2mm Lid:1.2-1.5mm	27	Base:black (opaque) Lid:black (opaque)
SSC -020L	0.2 L	0.17 L	65 x 55 x 100	Base: 1.2-4mm Lid: 1.2- 3.2mm	40	Base:colorless (translucent) Lid:yellow (opaque)
SSC -050L	0.5 L	0.425 L	74 x 74 x 114		56	
SSC -100L	1 L	0.85 L	100 x 100 x 155	Base:1.3-2.6mm Lid:1.3-1.5mm	84	Base: red (opaque) Lid: Colorless (Transparent)
SSC -150L	1.5 L	1.275 L	539 x 248 x 381		134	
SSC -100G	3.785 L	3.217 L	546 x 536 x 393	Base:1.3-3mm Lid:1.3-2 mm	486	
SSC -200G	7.571 L	6.435 L	517 x 355 x 387	Base:1.3- 4mm Lid:1.5-2.2mm	785	
SSC -300G	11.356L	9.653 L	355 x 304 x 558	Base:1.5- 4mm Lid:1.2-4mm	953	
SSC -400G	15.142L	12.871 L	398 x 317 x 463	Base:1.5- 4mm Lid:1.2-4mm	1625	
SSC -100Q	0.946 L	0.804 L	100 x 100 x 155	Base:1.3-2.6mm Lid:1.3-1.5mm	84	
SSC -200Q	1.892 L	1.608 L	565 x 314 x 387	Base:1.3-3mm Lid:1.3-2 mm	158	
SSC -500Q	4.73L	4.021 L	603 x 438 x 292	Base:1.3- 4mm Lid:1.5-2.2mm	523	

8 Similarities and Differences of the Proposed Devices to the Predicate Devices

The Promisemed Sharps Container is substantially equivalent to the predicate device, the Tiger Sharps Containers (K190240) in that these devices have same intended use, technological characteristics and method of manufacturer. Both the subject and predicate devices are disposable, non-sterile, single use devices. The differences between the subject device and predicate device do not affect the basic design principle, usage of the subject device.

A detailed comparison to the predicate is provided in Table 1.

	Subject Device	Predicate Device (K190240)	Comments
Trade Name	Promisemed Sharps Container	Tiger Sharps Containers	
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd	International Marketing Specialists Inc.	
Device Class	Class II	Class II	Same
Product Code	MMK	MMK	Same
Regulation number	880.5570	880.5570	Same
Regulation Name	Hypodermic single lumen needle.	Hypodermic single lumen needle.	Same
Intended Use/ Indications for Use	It is intended to be used for health care purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles and so on.	Tiger Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal. The Containers are single-use, disposable, non-sterile containers intended to be used for health-care purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target	Same

		population is for qualified personnel in health care facilities and other facilities in which medical sharps may be used. All device models are not for use in areas with unsupervised patient access.	
Capacity	0.05 litre/0.2 litre/ 0.5 litre/ 1 litre/1.5 litre/1 Quart/2 Quart/5 Quart/1 Gallon/2 Gallon/3 Gallon/4 Gallon	1 Quart / 5 Quart / 2 Gallon / 2 Gallon B/ 15 Liter/ 3 Gallon/ 8 Gallon	Different
Prescribed	OTC	OTC	Same
Weight range (g)	27-1625	109-1172	Different
No. of piece	2-3	2-3	Same
Material	Polypropylene	Polypropylene	Same
Color	Base: Red or yellow or black Lid: Transparent or black	Base: Red Lid: Transparent	Different
Clarity	Opaque/translucent	Opaque/translucent	Same
Non-sterile	Yes	Yes	Same
Method of manufacture	Injection Molded	Injection Molded	Same
Performance testing	Complied with ISO23907, ASTM F2132	Complied with ISO23907, ASTM F2132	Same
Disposable or Re-usable	Disposable	Disposable	Same

9 Performance Testing Summary

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- ASTM F2132-01(2008)
- ISO 23907-1
- 49 CFR 178.606 Stacking

- 49 CFR 178.608 Vibration

10 Conclusion

Based on the information provided within this 510(k) submission, proposed 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.