September 14, 2023

PureWay Compliance Inc.
Jeffery Miglicco
Director of Quality
201 Santa Monica Blvd, Suite 400
Santa Monica, California 90401

Re: K231484
Trade/Device Name: PureWay 1.4 Quart Sharps Collector
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: May 23, 2023
Received: May 23, 2023

Dear Jeffery Miglicco:

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231484

Device Name
PureWay 1.4 Quart Sharps Collector

Indications for Use *(Describe)*
PureWay Compliance 1.4 Quart Sharps Collector Container is single-use, disposable, non-sterile and intended to be used for healthcare purposes for safe containment and disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target user is for healthcare professionals.

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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510(k) Number: K231484
PureWay 1.4 Quart Sharps Collector

Device Information	*Comments*
Submitter	PureWay Compliance, Inc.
Headquarters	*1908 E. Dominguez St, Carson CA 90801*
Correspondent Contact Information	Jeffery Miglicco, Director of Quality E-mail: Jeffm@pureway.com Cell: 713.248.2289 Fax:
Device Common Name	*Sharps Container*
Device Classification Name	*Hypodermic single lumen needle (CFR 880.5570)*
Product Code	*MMK*
Classification	*Class II Device*
Classification Panel	*General Hospital*

Table 1: Device Information

Predicate Device Information *Sharps Container*	
Manufacturer Name	*Oakridge Products LLC.*
Common Name	*Sharps Container*
Premarket Notification NO.	*K130281*
Device Classification Name	*Hypodermic single lumen needle (CFR 880.5570)*
Product Code	*MMK*
Classification	*Class II Device*
Classification Panel	*General Hospital*

Table 2: Predicate Device Information

b. Date Prepared 05/23/2023

c. ***Description of Device***

The PureWay Sharps Collector is injection molded with High Density Polyethylene plastic (HDPE). Designed for single use, the container is puncture resistant, leak resistant on the sides and bottom, closable and stable. The container is labeled with a fill line and instructions for snapping

the container lid closed. “Do Not Overfill” to prevent overfill. The label is white and blue with white text and a black biohazard symbol is printed on a red background.

The container is made of two parts, (Base and Lid) that form a single unit. The red colored base is conical shaped**,** and the lid is a clamshell design snapped in place for a tight seal when the container is full.

The device is a non-sterile, single use, disposable infectious waste container and is designed to contain and hold sharps such as angio-caths, blood needles, lancets, cap needles, and various sized syringes. The shape of the container is conical which allows for one hand disposal of sharps and a clamshell lid for means of closure.

Product Description	Access Opening Size in Inches	Overall Size in Inches	Weight (grams)	Capacity at fill line
1.3 Quart	1.25 inch	7.75 x 3.9x 3.9	425	1 Quart

Table 3: Device Description

d. Indications for Use

PureWay Compliance 1.4 Quart Sharps Collector Container is single-use, disposable, non-sterile and intended to be used for healthcare purposes for safe containment and disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target user is for healthcare professionals.

e. Technological Characteristic Comparison

Characteristics	Predicate Device Oakridge 1 Quart Container (K130281)	PureWay 1.4 Quart Sharps Collector (K231484)	Comparison
Indication for Use	The Oak Ridge Products Sharps containers are single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and	The PureWay Sharps container is a single-use, disposable, non-sterile container intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and	Same
Use Location	The target population is for trained healthcare professionals.	The target population is for trained healthcare professionals.	Same
Material	Plastic Polypropylene	Plastic Polyethylene HDPE	Similar
	Material thickness .045" minimum	Material thickness .045" minimum	Same
	Injection Molded	Injection Molded	Same
	Color Red	Color Red	Same
Is Container Reusable or Single Use?	Single Use	Single Use	Same
Sterilization	Non-sterile	Non-sterile	Same
Design	Closable	Closable	Same
	Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping.	Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping.	Same
	Impact resistant	Impact resistant	Same
	Puncture resistant	Puncture resistant	Same
	Leak resistant	Leak resistant	Same
	Overfill indication	Overfill indication	Same
	Stable (maintaining upright position)	Stable (maintaining upright position)	Same
Dimensions			Same
Access opening and closure	Slide	Opening door	Same
Overall Size	4.5" x 4.5"x 7.5"	4.5" x 4.5" x 8"	Similar
Weight (grams)	115 grams	125 grams	Similar
Capacity at full line	.8 quarts	1.0 quarts	Similar
No features to bend, break or shear needle.	No feature present	No feature present	Same
Clarity	Minimum of one translucent component, either base or top	Minimum one translucent component either base or top	Same

The PureWay 1.3 quart sharps collector is intended use and technology to the predicate device, Oakridge Products LLC. 1 Quart Sharps Container *(*K130281).

Both devices are injection molded plastic, designed for single use, puncture resistant, impact resistance, leak resistant, closable, and stable. The container is labeled with a fill line and instructions for snapping the container lid closed.

Both containers are made of three parts, (Base, Lid, and Label) that form a single unit. The red colored base is conical shaped, and the lid is designed to snap in place for a tight seal.

Both devices are single use only and not sterile.

f. Summary of Non-Clinical Performance Data

Test Performed	Test Method/Applicable Standard (s)	Acceptance Criteria	Predicate Device (K130281)	PureWay 1.4 Quart (K231484)
Container stability	ISO 23907-1:2019 Section 5.1 Container stability	The container shall not topple over when tested.	Pass	Pass
Resistance to penetration	ISO 23907-1:2019 Section 5.3 Resistance to penetration	When tested the force needed to penetrate test specimens shall be a minimum of 16 N and an average of 18 N or greater.	Pass	Pass
Resistance to damage or leakage after dropping	ISO 23907-1:2019 Section 5.4 Resistance to damage and leakage after dropping	When tested there shall be no evidence of leakage and no breach of the sharp's containment area. Minimum five minutes after each topple, the following points shall be visually checked: 1. No evidence that the performance or function of the container has been compromised. 2. Container's temporary closure shall remain intact.	Pass Pass Pass	Pass Pass Pass
Resistance to damage or leakage after toppling	ISO 23907-1:2019 Section 5.5 Resistance to spillage by toppling	There shall be no evidence of breach of the sharps containment area. Minimum five minutes after each topple, the following points shall be visually checked: 1. There shall be no evidence that the performance or function of the container has been compromised. 2. The container's temporary closure shall remain intact	Pass Pass Pass	Pass Pass Pass
Fill line indicator	ISO 23907-1:2019 Section 4.2.7 Fill line indicator	1. Fill line shall be determined by the design of the container, taking into account the risk of sharps extending above the fill line, and shall be at a level no greater than 85 % of the total volume of the container. 2. Fill line feature helps prevent overfilling and is a critical safety feature of a sharps container. 3. It shall be possible to ensure the sharps are not above the fill line. This can be achieved either visually or mechanically.	Pass Pass Pass	Pass Pass Pass
Strength of Handles	ISO 23907-1:2019 4.2.2 and 5.2	1. All sharps containers shall be provided with one or several handles. 2. The handle/carrying feature shall not break or detach during testing. 3. The position of the handles(s), finger recesses, protrusions or flanges shall not interfere with the normal use of the container. 4. Fill the container with a mass equivalent to 150% of manufacturer's maximum allowable gross mass. Suspend the container by its handles(s) at the intended carrying points(s) from a rigid support for 1 h at a temperature of (23+/- 5) degrees Celsius. Remove the container from the support and inspect the handles for integrity and for any evidence of detachment of the handles(s) from the container.	N/A No Handles	Pass Pass Pass Pass, no evidence of detachment of the handles(s) from the container.

Bench testing has demonstrated that the device is in compliance with ISO 23907-1:2019 for Single Use Sharps Container and the expectation of the FDA Guidance Document, "Guidance on the content of Format of Premarket Notification (510(k)) submission for Sharps, dated October 1993.

g. Summary of Clinical Data: Not Applicable

h. Conclusion

The conclusions drawn for the non-clinical tests demonstrate that the device is as safe, as effective and performs as well as or better than the legally marketed predicate device.