October 14, 2025

PureWay Compliance Inc.
Jeffrey Miglicco
Chief Executive Officer
2717 Commercial Center Blvd
Ste 200
Katy, Texas 77494

Re: K251874
Trade/Device Name: PureWay Sharps Container 1-Gal, 2-Gal, 3-Gal (800011 800012, 800013)
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: September 9, 2025
Received: September 9, 2025

Dear Jeffrey 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 (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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.10.14 14:53:11 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251874

Device Name
PureWay Sharps Container 1-Gal, 2-Gal, 3-Gal(800011 800012, 800013)

Indications for Use *(Describe)*
The PureWay Sharps Container 1-Gal, 2-Gal, 3-Gal(800011 800012, 800013) are single-use, disposable, non-sterile containers intended to be used for healthcare purposes for the safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets, and blood needles. The target population is trained 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.

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

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*"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 K251874

| | |
|---|---|
| Submitter | PureWay Compliance, Inc. |
| Headquarters | 2717 Commercial center blvd, ste 200,<br>Katy, TX 77494 |
| Correspondent Contact Information | Jeffery Miglicco, Chief Executive Officer<br>E-mail: Jeffm@pureway.com<br>Cell: 713.248.2289 |
| Device Trade Name | PureWay Sharps Container 1-Gal, 2-Gal, 3-Gal (800011, 800012, 800013) |
| 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** | |
|---|---|
| Manufacturer Name | PureWay Compliance, Inc. |
| Device Trade Name | PUREWAY SHARPS COLLECTOR 1.2 GALLON, PUREWAY SHARPS COLLECTOR 2 GALLON, PUREWAY SHARPS COLLECTOR 3 GALLON |
| Premarket Notification NO. | K151249 |
| 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***

**Date Prepared** 10/09/2025

**Device Description**

The PureWay Sharps Container 1-Gal, 2-Gal, 3-Gal (800011 800012, 800013) is injection-molded with high-density polyethylene (HDPE) plastic. 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 with black text and a black biohazard symbol printed on an orange-red background.

The container is made of three parts (Base, Lid, and Label) that form a single unit. The red-colored base is conically shaped, and the lid features a clamshell design that snaps in place for a tight seal when the container is full.

The device is a non-sterile, single-use, disposable sharps infectious waste container designed to contain and hold sharps, such as angiocaths, blood needles, lancets, cap needles, and various-sized syringes. The shape of the container is conical and 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 Gallon | 4.07 x 7.47 inch | 11.19 x 8.38 x 4.75 | 294 | 1 Gallon (4 quarts) |
| 2 Gallon | 4.07 x 7.47 inch | 11.19 x 8.38 x 9 | 376 | 2 Gallon (8 quarts) |
| 3 Gallon | 4.07 x 7.47 inch | 11.19 x 8.38 x 15.5 | 458 | 3 Gallon (12 quarts) |

**Table 3: Device Description**

## Indications for Use

The PureWay Sharps Container 1-Gal, 2-Gal, 3-Gal (800011 800012, 800013) are single-use, disposable, non-sterile containers intended to be used for healthcare purposes for the safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets, and blood needles. The target population is trained healthcare professionals.

## Technological Characteristics Comparison

Technological Characteristics Comparison Table

| Characteristics | PureWay Sharps Container 1-Gal, 2-Gal, 3-Gal (800011 800012, 800013) | PureWay Sharps Collector 1.2 GALLON, PUREWAY SHARPS COLLECTOR 2 GALLON, PUREWAY SHARPS COLLECTOR 3 GALLON (Predicate K151249) | Comparison |
|---|---|---|---|
| Indications for Use | The PureWay Compliance 1-gallon, 2-gallon, and 3-gallon Sharps Collectors are single-use, disposable, non-sterile containers intended to be used for healthcare purposes for the safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets, and blood needles. The target population is trained healthcare professionals. | The PureWay® Sharps Collector Container is a disposable infectious waste container in 1.2 gallon, 2 gallon and 3 gallon sizes, intended for use in a healthcare setting. The PureWay® Sharps Collector Container will be ultimately destroyed through incineration. There are three indications for use statements corresponding to three sizes of container. These are reproduced below: Indications for Use Statement: 1.2 Gallon PureWay® Sharps Collector Container The empty | Similar |

| | | | |
|---|---|---|---|
| | | device, as it sits, is a red container that measures 10.75” x 6” x 7.27” and weighs 7oz. The aperture includes an insert which limits the opening to 1.25 inches in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in a healthcare setting. Indications for Use Statement: 2 Gallon PureWay® Sharps Collector Container The empty device, as it sits, is a red container that measures 10.75” x 6” x 11.15” and weighs 1lb 1oz. The aperture includes an insert which limits the opening to 1.25 inches in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in a healthcare setting. Indications for Use Statement: 3 Gallon PureWay® Sharps Collector Container The empty device, as it sits, is a red container that measures 10.75” x 6” x 15.73” and weighs 2 lbs. The aperture includes an insert which limits the opening to 1.25 inches in diameter. The intended use of the vertical entry, single use, sharps containers, is to provide a receptacle for used, contaminated medical sharps, and for enclosure during transport to ultimate disposal. The container is intended to be used in a healthcare setting. | |
| Use Location | Doctors offices, dental offices, emergency rooms, emergency vehicles, home healthcare and laboratories | Doctor's offices, dental offices, emergency rooms, emergency vehicles and labs for the safe disposal of hazardous sharps | Similar |
| Material | HDPE | Plastic Polypropylene | Similar |
| Is Container Reusable or Single Use? | Single use | Single use | Similar |
| Sterilization | Non-sterile | Non-sterile | Similar |

| | | | |
|---|---|---|---|
| Design | Sharps Container vertical drop aperture | Sharps container vertical drop aperture | Similar |
| Dimension | 1-Gallon 11.19"x 8.38" x 4.75"<br>2-Gallon 11.19" x 8.38 x 9"<br>3-Gallon 11.19" x 8.38 x 15.5" | 1.2-Gallon 10.75"x 6" x 7.27"<br>2-Gallon 10.75" x 6" x 11.15"<br>3-Gallon 10.75" x 6" x 15.73" | Similar |
| Access opening and closure | 1-Gallon, 2-Gallon and 3-Gallon have the same opening and closure which is 4.07" x 7.47" rectangular aperture at the top of the container allowing vertical and/or horizontal drop of sharps and is closed using a hinge lid. | 1.2-Gallon, 2-Gallon and 3-Gallon have the same opening and closure which is 2.75" circular aperture at the top of the container allowing vertical drop of sharps and is closed using a screw top lid. | Similar |
| Weight | 1-Gallon weight 294 g<br>2-Gallon weight 376 g<br>3-Gallon weight 458 g | 1.2-Gallon weight 330 g<br>2-Gallon weight 445 g<br>3-Gallon weight 565 g | Similar |
| Capacity at full line | 1-Gallon -> 1 Gallon at fill line<br>2-Gallon -> 2 Gallon at fill line<br>3-Gallon -> 3 Gallon at fill line | 1.2Gallon -> 1 Gallon at fill line<br>2-Gallon -> 2 Gallon at fill line<br>3-Gallon -> 3 Gallon at fill line | Similar |
| Color | Red body with white top | Red body with white top. | Similar |

## Performance Data (non-clinical)

The PureWay Sharps Container 1-Gal, 2-Gal, 3-Gal (800011 800012, 800013) have been bench tested and demonstrate compliance with the recognized consensus standard, ISO 23907-1:2019 for Single Use Sharps Container. The performance test includes Container Stability, Aperture Closure, Resistance to Penetration, and resistance to Leak. In addition, the FDA Guidance Document, "Guidance on the content of Format of Premarket Notification (510(k)) submission for Sharps, dated October 1993, was used to help identify applicable physical and mechanical features of the subject device.

**Non-Clinical Performance Test**

| Test Performed | Sample Size | Test Method/Applicable Standard (s) | Acceptance Criteria | Results Pass/Fail |
|---|---|---|---|---|
| **Container stability** | 3 | ISO 23907-1:2019 Section 5.1 Container stability | The container shall not topple over when tested. | Pass |

| | | | | |
|---|---|---|---|---|
| **Strength of Handles** | 3 | ISO 23907-1:2019 Section 4.2.2 & 5.2 | The container must be robust enough to support the container's mass when filled to the nominal fill line. Allow the user to carry the container safely without risk or breakage and prevent tipping or dropping. Must withstand 25lbs (or specified load) without failure.<br><br>Maximum weight and tested weight per system<br>1 gallon system tested – 7 lbs. Max weight / 7 lbs. tested<br>2-gallon system tested – 14 lbs. Max weight / 14 lbs. tested.<br>3-gallon system tested – 21 lbs. Max weight / 21 lbs. tested. | Pass<br><br>Pass<br><br>Pass<br><br>Pass |
| **Resistance to penetration** | 24 | 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 |
| **Resistance to damage or leakage after dropping** | 5 | 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:<br>1.No evidence that the performance or function of the container has been compromised.<br><br>2.The container's temporary closure shall remain intact. | Pass<br><br>Pass<br><br>Pass |

| | | | | |
|---|---|---|---|---|
| **Resistance to damage or leakage after toppling** | 3 | ISO 23907-1:2019 Section 5.5 Resistance to spillage by toppling | There shall be no evidence of a breach of the sharps containment area.<br>Minimum five minutes after each topple, the following points shall be visually checked:<br>1.There shall be no evidence that the performance or function of the container has been compromised.<br>2.The container's temporary closure shall remain intact | Pass<br><br>Pass<br><br>Pass |
| **Fill line indicator** | 1 | ISO 23907-1:2019<br>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.<br>2. The fill line feature helps prevent overfilling and is a critical safety feature of a sharps container.<br>It shall be possible to ensure the sharps are not above the fill line. This can be achieved either visually or mechanically. | Pass<br><br>Pass<br><br>Pass |

**Conclusion:**

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device, K151249.