



Food and Drug Administration
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September 4, 2015

PureWay Compliance, Inc.
Jeffery Miglicco
VP of Sales & Operations
201 Santa Monica Blvd. Suite 400
Santa Monica, CA 90401

Re: K151249
Trade/Device Name: PureWay® Sharps Collector Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: August 7, 2015
Received: August 10, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Division of Anesthesiology,
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Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151249

Device Name
PureWay® Sharps Collector Container

Indications for Use (Describe)

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 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 11lb 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.

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.

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5. 510 (k) Summary

a. Submitter	PureWay Compliance, Inc.
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Regional Office	20501 Katy Freeway, Suite 206 Katy, TX 77450 Main: 877.765.3030 ext. 118 Cell: 713.248.2289 Fax: 310.752.1944
Manufacturing site	1908 East Dominguez Street Carson, CA 90810
Contact Person:	Jeffery Miglicco, VP of Sales & Operations E-mail: Jeffm@pureway.com

b. Date prepared 4/22/15

c. Device Identification

<u>Trade or Proprietary Name</u>	PureWay® Sharps Collector Container
Common Name	Sharps Containers
510(k) number	K151249
Classification Name	Hypodermic single lumen needle (CFR: 880.5570)
Product code	MMK
Classification	Class II device
Classification Panel	General Hospital

d. Predicate Device

GRP Sharps Container 510(k) number K132476

e. Device -Description

The PureWay® Sharps Collector container is blow molded with High Density Polyethylene plastic and is available in 1.2 Gallon, 2 Gallon and 3 Gallon sizes. The containers are identical except for capacity. The device has a circular opening at the top with an insert to prevent hand access and items from falling out. The insert is made of Low Density Polyethylene plastic, is also circular limiting the opening to 1.25 inches. The opening allows for a vertical sharps drop. Once the PureWay® Sharps Collector container is full, the cap is placed on top of the opening and screwed close for a tight seal.

Each container is non-sterile, single use, disposable sharps container (disposable infectious waste container).



The containers are designed to contain and hold sharps such as angio-caths, blood needles, lancets, cap needles, and various sized syringes. The shape of the container will be rectangular and the only access to the container is through the screw top opening or aperture.

In summary, all PureWay® Sharps Collector containers are blow molded using High Density Polyethylene plastic, non-sterile, disposable, sharps containers (infectious waste container). All the devices allow for one-handed disposal of sharps and offer a means of closure.

f. *Indications for Use*

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 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 11lb 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.

Directions for use

1. Carefully place sharps into container
2. Do not fill past line on container
3. Seal the container with the lid provided
4. Destroy by incineration

g. Standards & Test Methods

The following FDA recognized standards were used in the preparation of this 510(k)



Standards	Standard section	Validation test conducted
ISO 23907 First edition 2012-09-01 Sharps injury protection - Requirements and test methods - Sharps containers	5.1 container stability	Container filled to fill line and placed in the most adverse position for toppling on a surface with a minimum inclination angle of 15 degrees.
	5.2 Strength of handle(s)	Fill the container with a mass equal to 150% of maximum allowable gross mass, close the container and suspend the container by its handle(s) at the intended carrying point(s) from a rigid support for 1 hour at a temperature of (23+/- 5) degrees Celsius.
	5.3 resistance to penetration	Test the thickness and strength of the container at the worst-case area for needle penetration.
	5.4 Resistance to damage and leakage after dropping	The container is dropped minimum height of 1m(39.5") at a specified temperature on all sides of the container.

h. Comparison of Technological Characteristics with the Predicate Device

The following table compares the PureWay® Sharps Collector container to the GRP Sharps Container with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A - Comparison of Characteristics

Manufacturer	PureWay Compliance	GRP and Associates
Trade Name	PureWay® Sharps Collector	GRP Sharps Container, models 1G, 2G and 3G
Common/Usual Name	Sharps Container	Sharps Container
510(k) Number	K151249	K132476
Product Code	MMK (same)	MMK
Classification	21CFR 880.5570 (same)	21 CFR 880.5570
Classification Name	Hypodermic single lumen needle	Hypodermic single lumen needle
Indications for Use	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.	The empty device, as it sits, is a red container that measures comes in three different sizes 1 gallon, 2 gallon and 3 gallon. 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 hospitals, clinics, operating rooms, and laboratories by technicians, doctors, dentist, and veterinarians.
Product classification	Class II –(Same)	Class II
Labeling: Biohazard labels visible on device	Yes (same)	Yes



Disposal procedures including in labeling	Yes (same)	Yes
Assembly, mounting procedures	None. Free standing on wide rectangular base (same)	None. Free standing on wide base
Operating Instructions	Yes – IFU – (Same)	Yes - IFU
Device Description & Volume	1.2 gallon, 2 gallon, and 3 gallon sharps containers (similar)	1.5 Qt, 1 gallon, 2 gallon, and 3 gallon sharps containers
Materials of Construction	Blow molded HDPE (High Density Polyethylene) (same)	Blow molded HDPE
Color	Red, opaque (same)	Red, opaque
Puncture Resistance	YES	YES
Closure	1.25" circular aperture at the top of the container allowing vertical drop of sharps and is closed using a screw top lid – (similar)	Spun-weld iris, functions as an aperture allowing vertical drop of sharps
Leak-proof on sides and bottom	YES	YES
Labeled or color-coded	Labeled and color coded, biohazard labeled. Picture provided below – (same)	Labeled and color coded, biohazard labeled
Single use or reusable	Single Use (same)	Single Use
Intended location	The container is intended to be used in a healthcare setting.	The container is intended to be used in nursing homes, doctor's offices, dental offices, emergency room, emergency vehicles and labs for the safe disposal of hazardous sharps
Includes features to bend, break or shear needles	No (same)	No
Container full indication	Yes - clearly marked fill line on container (same)	Yes - clearly marked fill line on container



Non-Clinical Performance Data

The PureWay® Sharps Collector container has been performance tested and demonstrates compliance with the recognized consensus standard, ISO 23907 First edition 2012-09-01 Sharps injury protection – Requirements and test methods – Sharps containers (Stability, Handle Strength, Penetration, Handling and Leak Resistance). 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.

Testing was conducted in accordance with:

- ISO 23907 First edition 2012-09-01 Sharps injury protection – Requirements and test methods – Sharps containers (Stability, Handle Strength, Penetration, Handling and Leak Resistance)
- CSA Z316.6-07 – Evaluation of single-use and reusable medical sharps containers for bio hazardous and cytotoxic waste – Fill Capacity
- ASTM F2132-01

The performance testing demonstrates compliance with all the recognized consensus standards listed above. Testing results show the PureWay® Sharps Collector containers (sizes 1.2, 2 and 3 gallon) pass all applicable and required tests. An independent testing laboratory performed all the test listed in this section according to the standards requirements. Additional testing data is presented in the performance testing section. In addition, the FDA Guidance Document “Guidance on the Content of Format of Premarket Notification (510(k)) submissions for Sharps, dated October 1993, was used to help identify applicable physical and mechanical features of the subject device.

i. Conclusion

The subject device is substantially equivalent to the predicate device.