MAUSER USA LLC, 2 Tower Center Drive 20th floor, East Brunswick, New Jersey 08816 USA

510K SUMMARY

5. 1 SUBMITTER

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5.2 DEVICE NAME AND CLASSIFICATION

Common name:	Sharps container
Classification Name:	Hyperdermic single lumen needle
Classification Regulations:	21 CFR 880.5570, Class II
Product Code:	MMK
Trade/Proprietary Name:	MAUSER PG II Sharps Container

5.3 PREDICATE DEVICE

MAUSER PG II Sharps Container is substantially equivalent in indications and design principle to the following predicate devices

- Oak Ridge Products LLC. Sharps Containers (K130281)
- Oak Ridge Products LLC. Multi-purpose Sharps Containers (K141759)

5.4 DEVICE DESCRIPTION

MAUSER PG II Sharps Container is a single-use device, which consist of rectangular body and available in three sizes 30 liter, 50 liter and 60 liter. Each container has two parts, the body and the lid, which assemble together to form a unit. Two lid styles are available: grip, and click with port hole.

MAUSER PG II Sharps Container is designed for use on sites with no unsupervised patient access.

Manufacturer offers a stainless steel pedal frame cart that offers a hands free collection process and integrates with all sizes of container and lid type.

The container is designed for safe collection and disposal of sharps, i.e. items that can cause puncture wounds, cuts or tears in skin or mucous membranes, including, but not limited to

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hypodermic, surgical, suture, and IV needles; Pasteur pipets, lancets, razors, scalpels, and other blades.

The following MAUSER PG II Sharps Container models and accessories are described in this submission:

Model or part	Product Description and Closure Type	Overall size (mm)	Aperture (mm)
060V4080RO 060V4080GE 060V4080Z0 060V4080WI	MAUSER PG II Sharps Container, 60 liter, Grip lid (Red, Yellow, Black, White w/blue lid)	(L) 376 x (W) 309 x (H) 640	(L) 375 x (W) 305
050V4080RO 050V4080GE 050V4080ZW 050V4080WI	MAUSER PG II Sharps Container, 50 liter, Grip lid, (Red, Yellow, Black, White w/blue lid)	(L) 376 x (W) 309 x (H) 534	(L) 375 x (W) 305
030V4080RO 030V4080GE 030V4080ZW 030V4080WI	MAUSER PG II Sharps Container, 30 liter, Grip lid (Red, Yellow, Black, White w/blue lid)	(L) 376 x (W) 309 x (H) 312	(L) 375 x (W) 305
060V4080RO 060V4080GE 060V4080Z0 060V4080WI	MAUSER PG II Sharps Container, 60 liter, Click lid w/porthole (Red, Yellow, Black, White w/blue lid)	(L) 376 x (W) 309 x (H) 640	(L) 375 x (W) 305(Major) 152 (porthole diameter)
050V4080RO 050V4080GE 050V4080ZW 050V4080WI	MAUSER PG II Sharps Container, 50 liter, Click lid w/porthole (Red, Yellow, Black, White w/blue lid)	(L) 376 x (W) 309 x (H) 534	(L) 376 x (W) 309(Major) 152 (porthole diameter)
030V4080RO 030V4080GE 030V4080ZW 030V4080WI	MAUSER PG II Sharps Container, 30 liter, Click lid w/porthole (Red, Yellow, Black, White w/blue lid)	(L) 376 x (W) 309 x (H) 312	(L) 376 x (W) 309(Major) 152 (porthole diameter)
710374 (Red) 710371(Black) 710258 (Yellow) 710303 (Blue)	Grip lid	(L) 395.5 x (W) 329	NA
700260 (Red) 700156 (Black) 700256 (Yellow) 700901(Blue)	Click lid w/porthole	(L) 395.5 x (W) 329	152 (porthole diameter)
N/A	Steel pedal bin frame	N/A	N/A

5.5 INDICATIONS FOR USE

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MAUSER PG II Sharps Container is intended to be used in healthcare facilities including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, veterinarian offices and other waste generators for the safe collection and disposal of hazardous sharps.

MAUSER PG II Sharps Container is designed for use on sites with no unsupervised patient access.

The single-use, non-sterile device is intended for over-the-counter use. The manufacturer's pedal bin frame is required if the device is used on medication carts. The pedal bin frame cart is constructed of stainless steel and comes fully preassembled. The cart offers a hands free collection option and fully integrates with all sizes of container and lid styles.

The full containers are collected and transported by a licensed health care waste contractor for disposal in accordance with federal and state regulations.

5.6 EQUIVALENCE TO MARKETED DEVICE

MAUSER USA, LLC. Submits the following information in this premarket notification to demonstrate, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indication and design principle to the following legally marketed predicate device:

- Oak Ridge Products LLC. Sharps Containers (K130281)
- Oak Ridge Products LLC. Multi-purpose Sharps Containers (K141759)

	Subject Device	**Predicate Device**	**Predicate Device**
	MAUSER PG II Sharps Container MAUSER USA, LLC. 2 Tower Center Drive, 20th floor East Brunswick, NJ 08816 USA	Oak Ridge Products Sharps Containers (K130281) Oak Ridge Products L.L.C 4612 Century Court McHenry, Illinois, 60050 USA	Oak Ridge Products Multi-purpose Sharps Containers (K141759) Oak Ridge Products L.L.C 4612 Century Court McHenry, Illinois, 60050 USA
Target population	Healthcare professionals	Healthcare professionals	Healthcare professionals
Indication for use	MAUSER PG II Sharps Container is intended to be used in healthcare facilities including nursing stations, medication carts,	Oak Ridge Products Sharps containers are single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous	Oak Ridge sharps containers are intended to be used for the safe disposal of hazardous sharps

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	laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, veterinarian offices and other waste generators for the safe collection and disposal of hazardous sharps.	sharps such as hypodermic needles, syringes, lancets, and blood needles.	
Performance	Single use	Single use	Single use
Manufacturing	Injection molded	Injection molded	Injection molded
Materials of construction	Polypropylene	Polypropylene	Polypropylene
Color	Red, yellow, black, white	Red, natural	Red
Sharps elimination	Sharps inserted through the top	Sharps inserted through the top	Sharps inserted through the top
Method of visualizing the fill line	Large apertures opening provides clear and unrestricted view of fill line	A translucent container component provides view of fill line	A translucent container component provides view of fill line
Mounting Accessory	Available for use on medication carts	Available and necessary for 1 quart and 5.4 quart models	Unknown
Impact resistance (Drop test)	Yes	Yes	Yes
Vibration test	Yes	Unknown	Unknown
Stack test	Yes	Unknown	Unknown
Puncture resistance	Yes	Yes	Yes
Leak Resistance	Yes	Yes	Yes

5.7 PERFORMANCE DATA

No FDA performance standard for MAUSER PG II Sharps Container have been established. The following tests were performed to ensure that the performance of the subject device meets MAUSER USA, LLC. requirements.

	Test	Test Method	Results
1	Puncture resistance	ASTM F2132-01[2] (Reapproved 2008)	Pass
2	Drop test (Impact resistance)	§178.603[1]	Pass
3	Leak resistance test	§173.197[1] Regulated medical waste	Pass
4	Stack Test	§178.606[1] (c) (1)	Pass

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5	Vibration Test	§178.608[1]	Pass
6	Stability	ISO 23907[3]	Pass
7	Strength of handles	ISO 23907[3]	Pass

[1]United States Department of Transportation Code of Federal Regulations (CFR) Title 49, Transportation, Parts 100-199
[2] Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps
[3]Sharps Injury Protection – Requirements and test methods – Sharps Containers (First Edition 2012-09-01)

Puncture resistance – ASTM F2132-01 (Reapproved 2008) Standard Specification for Puncture Resistance of Materials used in Containers for Discarded Medical Needles and Other Sharps.

Puncture resistance was measured by taking various sections of container and subjecting them to penetration with a 21 gage by 1 inch needle. The force required to puncture the container was measured. The puncture resistance of each section of the container was greater than 15 N and the passing criterion was met.

Drop test - §178.603 (United States Department of Transportation Code of Federal Regulations (CFR) Title 49, Transportation, Parts 100-199)

Drop test was conducted by filling six containers to maximum authorized gross mass (60 liter -30 kg; 50 liter -28 kg; 30 liter -15 kg) with simulated medical waste. The containers were then conditioned at -18^0 C for 24 hours and dropped in specific orientations from a height of no less than 1.2 meters. No release of contents was observed and the passing criterion was met.

Leak resistance test - §173.197 Regulated medical waste (United States Department of Transportation Code of Federal Regulations (CFR) Title 49, Transportation, Parts 100-199)

Leak resistance was conducted by filling container to rated liquid capacity with water. The containers were then closed as per closing instructions and positioned upside down on cardboard paper to show any evidence of leaking. Containers remained upside down for 60 minutes while being observed for leakage. No leakage was observed and the passing criterion was met.

Stack test - §178.606 (c) (United States Department of Transportation Code of Federal Regulations (CFR) Title 49, Transportation, Parts 100-199)

Containers were filled to the required test capacity and closed as for shipment. Each container was subjected to a force applied to the top surface equivalent to the total weight of identical packages which might be stacked on it during transport. The minimum height of the stack, including the test sample, was 3 meters. Upon completion of the stack test, containers were observed for deformation. The containers did not deteriorate or release contents, and the passing criteria were met.

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Vibration test - §178.608 (United States Department of Transportation Code of Federal Regulations (CFR) Title 49, Transportation, Parts 100-199)

Containers were filled with simulated medical waste, closed as for shipment and placed on vibration table. The containers were then vibrated sing a vibration platform with a 1 in. vertical peak-to-peak displacement, for 60 minutes at a frequency that causes them to be raised enough such that a piece of material 1.6-mm thick can be passed between the container and the vibration platform. The containers did not rupture, leak or deteriorate, and the passing criteria were met.

Container Stability – ISO 23907 (Sharps Injury Protection – Requirements and test methods – Sharps Containers, First Edition 2012-09-01)

Container stability was evaluated by filling containers with a material of density 0.20+/-0.01 kg/l and placed on an incline with a minimum angle of 15°. Testing was conducted for each side of the container. The container did not slide or topple and the passing criteria were met.

Strength of Handles - ISO 23907 (Sharps Injury Protection – Requirements and test methods – Sharps Containers, First Edition 2012-09-01)

Handle strength was measured by filling container to 150% of its authorized gross mass and suspending it from handles for an hour at 23+/-5°C. The containers remained intact and handles did not rupture, tear, crack, or separate from the container and the passing criteria were met.

Clinical data were not submitted in this premarket notification

5.8 CONCLUSION

MAUSER PG II Sharps Container is substantially equivalent to Oak Ridge Products Sharps Container and Oak Ridge Products Multi-purpose Sharps Container (K130281 and K141759).