

K960525

**510 (k)  
SUMMARY**

**Submitter's Name:** Bemis Health Care  
**Address:** 300 Mill Street  
Sheboygan Falls, WI 53085  
**Telephone:** 414-467-4621  
**Contact Person:** John B. Howell  
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**Name of Device**

Common Name: Sharps Disposal Container  
Trade name: ***Bemis One Quart Phlebotomy Container***  
Classification Name: Sharps Disposal Container  
**Predicate Device:** Bemis Phlebotomy Container

**Description of the Device**

The One Quart Phlebotomy Container has a volume of 1.0 qt. and weigh .02 lb (3.2oz.) with dimensions of 8"H x 4.3"W x 4.3"D. One Quart Phlebotomy Containers are injection molded with polypropylene plastic in translucent red. These products are typically a .070" wall thickness. The One Quart Phlebotomy containers are NOT reusable.

The One Quart Phlebotomy Containers are puncture-resistant, injection-molded containers with integral sidewalls and bottom. They are leakproof on the sides and bottom.

They are labeled with the Biohazard warning symbol. The label color is orange-red, with lettering and symbol in contrasting color in accordance with OSHA regulations. The labels are attached directly to the surface of the container by a permanent adhesive.

The One Quart Phlebotomy Container is secured to a tray or table top in an adhesive-backed injection molded plastic base.

There are no features to bend, break, or shear the needle.

The lid incorporates a "needle key" which can be used to unscrew needles from blood collection tube holders. After blood collection, the needle is inserted into the slotted opening and slid forward until firmly seated, and turned to unscrew the needle from the tube holder.

The lid has two openings: one intended to accommodate blood tube needles only and the other, larger opening to accept larger sharps such as butterfly needles. Both openings have covers that may be temporarily closed during transportation. Each cover also has a tab that is inserted in slots for final locking closure for disposal.

**Statement of intended use**

The Bemis One Quart Phlebotomy Container is a sharps disposal container. It is intended for the safe disposal of needles and syringes in areas with or without controlled access. They are typically used in patient rooms, nurse's stations, doctors' and dentists' offices and on med carts.

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**COMPARISON TO PREDICATE DEVICE**

**Bemis One Quart Phlebotomy Container      Equivalent: Bemis Phlebotomy**

Impact Resistance:  
PASS

Impact Resistance:  
PASS

Puncture Resistance:  
PASS

Puncture Resistance:  
PASS

Overfill Detection:  
PASS

Overfill Detection:  
FAIL

Leak Resistance:  
PASS

Leak Resistance:  
PASS

Sharps Access and Closure:  
PASS

Sharps Access and Closure:  
PASS

Stability in Upright Position:  
PASS

Stability in Upright Position:  
PASS

Handling:  
PASS

Handling:  
PASS

Capacity:  
1qt.

Capacity:  
0.5 qt.

Feature to Minimize Aerosolization:  
Two lids with temporary snap closure

Feature to Minimize  
Aerosolization:  
Slide Top

**Conclusion**

The conclusion drawn from our testing is that the Bemis One Quart Phlebotomy Container is as safe and effective as the legally marketed Bemis Phlebotomy Container.