510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92

Preparation Date: February 24, 2014

ADMINISTRATIVE INFORMATION

Submitted by: Bradford Wright Companies, Inc.
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President
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DEVICE IDENTIFICATION

510(k) Number: K131708
Device Name: BWCSH-1
Common Name: Sharps Container
Classification Name: MMK
CFR Reference: Accessory to hypodermic single lumen needles
Classification Panel: General Hospital

This submission is the first and only existing FDA filing by this manufacturer. We have never marketed the device in the U.S.
Indications for Use:

The BWCSH-1 sharps container has a one-gallon fill line capacity that is intended to be used for the safe disposal of hazardous sharps. The BWCSH-1 sharps container is metallic canister fitted with thermal plastic top and has an orange-red biohazard label adhered to the containers with fill line printed on the front. The BWCSH-1 device is for single use, disposable and is not a secondary container. The BWCSH-1 sharps container dimensions are 10.5 inches in width at the top, 4.75 inches deep and 8.25 inches in height. BWCSH-1 sharps container weighs 1.075 pounds when empty.

Predicate Device:

510(k) Number: K982781
Trade Name of Device: Demolizer #47 1 Gal. Point of Generation Sharps Container
Common Name: Sharps Container
Classification Name: Accessory to hypodermic single lumen needles
CFR Reference: 21CFR 880.5570- Class II
Classification Panel: General Hospital

Legally Marketed Equivalent Devices:

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>510(k) #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demolizer #47 1 Gallon Point of Generation Sharps Container</td>
<td>Thermal Waste Technologies, Inc.</td>
<td>K982781</td>
</tr>
<tr>
<td>B-D Guardian™ Nestable Sharps Collectors</td>
<td>Becton Dickinson &amp; Co.</td>
<td>K 943575</td>
</tr>
</tbody>
</table>
DEVICE DESCRIPTIVE INFORMATION

Product Description:

The BWCSH-1 sharps container has a one-gallon fill line capacity that is intended to be used for the safe disposal of hazardous sharps. The BWCSH-1 sharps container is stable, puncture resistant, impact and shatter resistant, and leak-proof on the sides and bottom. The BWCSH-1 container is fitted with a rotating top, allowing safe one-handed disposal of used sharps. The container has a locking tamper resistant plastic lid that once snapped in place, cannot be manually removed. Labels are orange-red with black text and a black biohazard symbol printed on a white background. Labels are adhered to the containers at the time of manufacture with the fill line printed. The BWCSH-1 device is for single use, disposable and is not a secondary container.

The BWCSH-1 sharps container three main components are nested together to reduce storage and shipping requirements. The rotating top is made with uncolored translucent material. The translucent nature of the product allows for a visual determination of content level. The bottom of the rotating top's internal chute matches the fill line to physically prevent over filling.

The BWCSH-1 device underwent and passed performance testing that consisted of confirming its key safety and reliability aspects. The following four types of performance tests were performed:

- Puncture Resistance Testing - According to ASTM F2132-01(2008);
- Leak-Proof Testing - According to 29 CFR 1910.1030(d)(2)(viii)(c);
- Impact and Shatter Resistance - According to ISO 23907:2012 and

General Specification Table

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Access opening size</th>
<th>Access opening and closure</th>
<th>Overall Size L x W x H (inches)</th>
<th>Weight (pounds)</th>
<th>Capacity at full line</th>
</tr>
</thead>
<tbody>
<tr>
<td>BWCSH-1</td>
<td>9&quot; x 1.75&quot;</td>
<td>Rotating door and tamper resistant locking lid</td>
<td>10.5 x 4.75 x 8.25</td>
<td>1.075</td>
<td>1 Gallon</td>
</tr>
</tbody>
</table>
Table showing sharps container component dimensions:

<table>
<thead>
<tr>
<th>Component</th>
<th>Material</th>
<th>Depth (inches)</th>
<th>Width (inches)</th>
<th>Height (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canister at Top</td>
<td>Tinplate Steel</td>
<td>4&quot;</td>
<td>10&quot;</td>
<td>8&quot;</td>
</tr>
<tr>
<td>Canister Bottom</td>
<td>Tinplate Steel</td>
<td>3&quot;</td>
<td>9&quot;</td>
<td>N.A.</td>
</tr>
<tr>
<td>Sharps Chute closed</td>
<td>molded Polypropylene</td>
<td>4 3/4&quot;</td>
<td>10 1/2&quot;</td>
<td>2 1/4&quot;</td>
</tr>
<tr>
<td>Sharps Chute alone</td>
<td>molded Polypropylene</td>
<td>3 3/4&quot;</td>
<td>9 1/2&quot;</td>
<td>2&quot;</td>
</tr>
<tr>
<td>Top Rim</td>
<td>molded Polystyrene</td>
<td>4 3/4&quot;</td>
<td>10 1/2&quot;</td>
<td>1/4&quot;</td>
</tr>
<tr>
<td>Lid Plug</td>
<td>molded Polystyrene</td>
<td>3 3/4&quot;</td>
<td>9 3/4&quot;</td>
<td>1/2&quot;</td>
</tr>
<tr>
<td>Sharps Container</td>
<td>Metal &amp; Plastic</td>
<td>4 3/4&quot;</td>
<td>10 1/2&quot;</td>
<td>8 1/4&quot;</td>
</tr>
</tbody>
</table>
**PREDICATE DEVICES:**

(K982781) Demolizer #47 One-Gallon Point of Generation Sharps Container by Thermal Waste Technologies, Inc. and (K943575) B-D Guardian™ Nestable Sharps Collectors by Becton Dickinson & Co. are substantially equivalent to the applicant's BWCSH-1 Sharps Container.

**Comparison table with predicate device:**

<table>
<thead>
<tr>
<th>Element of Comparison</th>
<th>Subject Device</th>
<th>Predicate Device #1</th>
<th>Predicate Device #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Name</td>
<td>BWCSH-1 Sharps Container</td>
<td>Demolizer #47 One-Gallon Point of Generation Sharps Container</td>
<td>B-D Guardian™ Nestable Sharps Collectors</td>
</tr>
<tr>
<td>FDA 510(k) Number</td>
<td>K131708</td>
<td>K982781</td>
<td>K943575</td>
</tr>
<tr>
<td>Intended Use(s)</td>
<td>BWCSH-1 sharps container is intended to be used for the safe disposal of hazardous sharps.</td>
<td>Intended for the disposal of various-sized contaminated medical sharps (including needles, syringes, slides, and ampoules) in clinical and laboratory healthcare settings.</td>
<td>B-D sharps containers are intended to be used for the safe disposal of hazardous sharps</td>
</tr>
<tr>
<td>Target Population</td>
<td>Healthcare professional</td>
<td>Healthcare professional</td>
<td>Healthcare professional</td>
</tr>
<tr>
<td>Where Used</td>
<td>Healthcare Facilities</td>
<td>Intended for clinical, nonclinical healthcare settings such as laboratories, dentists' office, doctor's office, corporate clinics and nursing homes.</td>
<td>Healthcare Facilities</td>
</tr>
<tr>
<td>Material</td>
<td>Polypropylene, Polystyrene &amp; Tinplate steel</td>
<td>Tinplate steel</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>Sharps Access</td>
<td>Sharps inserted through the top</td>
<td>Sharps inserted through the top</td>
<td>Sharps inserted through the top</td>
</tr>
<tr>
<td>Sharps Closure</td>
<td>Lid is locked in place for removal</td>
<td>Closure feature is closed then locked</td>
<td>Flaps are closed and locked in place</td>
</tr>
<tr>
<td>Feature</td>
<td>Yes</td>
<td>Not tested</td>
<td>Yes</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-----</td>
<td>------------</td>
<td>------</td>
</tr>
<tr>
<td>Impact Resistance</td>
<td>Yes</td>
<td>Not tested</td>
<td>Yes</td>
</tr>
<tr>
<td>Puncture Resistance</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Leak Proof</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Non-sterile</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Single Use</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Capable of maintaining a stable, upright position</td>
<td>Yes</td>
<td>Not tested</td>
<td>Yes</td>
</tr>
<tr>
<td>No features to bend, break, or shear needle.</td>
<td>No Feature Present</td>
<td>No Feature Present</td>
<td>No Feature Present</td>
</tr>
<tr>
<td>Reusable Sharps Containers</td>
<td>Labeling is “Single Use”</td>
<td>Labeling is “Single Use”</td>
<td>Labeling is “Single Use”</td>
</tr>
<tr>
<td>Overfill Indication</td>
<td>Labeled “Do Not Fill Above This Line”</td>
<td>Labeled “Do Not Fill Above This Line”</td>
<td>“Do Not Overfill” or “Fill to this Level Only” is labeled or embossed on the container at the location of the overfill. Labeling includes a “Fill Line”</td>
</tr>
<tr>
<td>Clarity</td>
<td>Each Container has a minimum of one translucent component, either base or top</td>
<td>Temporary/Permanent Opening for visual inspection.</td>
<td>Each Collector has a minimum of one translucent component, either base or top</td>
</tr>
<tr>
<td>Construction</td>
<td>Injection Molded Lid and Rotating top and 2 piece seamed &amp; glued tinplate base</td>
<td>3 piece seamed &amp; glued tinplate base</td>
<td>Injection Molded Containers, Lids and Closure</td>
</tr>
<tr>
<td>Dimensions</td>
<td>10.5 inches by 4.75 inches by 8.25 inches</td>
<td>6.5 inches in diameter by 8 inches</td>
<td>12 inches by 13.5 inches by 6 inches</td>
</tr>
<tr>
<td>Fill Capacity</td>
<td>One US gallon</td>
<td>One US gallon</td>
<td>7.6 Liters (2.01 US gallons)</td>
</tr>
</tbody>
</table>
SUBSTANTIAL EQUIVALENCE DISCUSSION of Similarities and Differences:

The BWCSH-1 Sharps Container is similar to both the Demolizer #47 One-Gallon Point of Generation Sharps Container and the B-D Guardian™ Nestable Sharps Collectors in:

- Intended use
- Target Population
- Materials
- Design
- Performance testing

Intended use comparison:

The intended use of the new BWCSH-1 Sharps Container is the same as both predicate devices. BWCSH-1 sharps container is intended to be used for the safe disposal of hazardous sharps.

Design and Material Comparison:

The design and functional characteristics of the BWCSH-1 Sharps Container and both predicate devices are similar. The BWCSH-1 Sharps Container and the B-D Guardian™ Nestable Sharps Collectors predicate device’s parts are nestable, whereas the Demolizer #47 One-Gallon Point of Generation Sharps Container is not. When assembled all form a single unit. BWCSH-1 Sharps Container and the B-D Guardian™ Nestable Sharps Collectors predicate device both have features to prevent contact between user and the contents and all are designed for a visual determination of the maximum capacity. None of the devices have features that bend, break, or shear needles. BWCSH-1 Sharps Container and both predicate devices are all designed for single use by a locking feature in the lids and closure or access door. BWCSH-1 Sharps Container’s lid and sharps chute as well as the B-D Guardian™ Nestable Sharps Collectors predicate device are constructed of polymeric materials which are injection molded. The material of construction differs from the B-D Guardian™ Nestable Sharps Collectors is the BWCSH-1 Sharps Container’s lower canister is made of seamed and glued tin plated steel same as the whole Demolizer #47 One-Gallon Point of Generation Sharps Container predicate device. BWCSH-1 Sharps Container and the predicate devices all allow for a visual determination of content level.

Summary of Non-Clinical Performance Bench Testing:

Performance Standards:

The Recognition Number 6-293 identifies ISO 23907 First Edition 2012-09-01, "Sharps injury protection - Requirements and test methods - Sharps containers".


In addition the relevant FDA guidance document, "Guidance on the Content and Format of Premarket Notification [510(k)] Submission for Sharps Collectors dated October 1993", was used to identify applicable physical and mechanical features of the BWCSH-1 Sharps Container and predicate devices. All applicable standards have been used to show that the BWCSH-1 Sharps Container is substantially equivalent to the appropriately listed predicate devices.

The performance testing summary demonstrates substantial equivalence between the BWCSH-1 Sharps Container and the predicate devices. The BWCSH-1 Sharps Container has been tested by appropriate methods with respect to the relevant standards; FDA recognized ASTM standards F2132-01 and OSHA regulations 29 CFR Part 1910:1030. No new issues of safety and effectiveness were raised with the testing performed, and the BWCSH-1 Sharps Container is considered substantially equivalent to its predicate device.

Performance Testing (Bench) - Product Testing

The BWCSH-1 Sharps Container incorporates equivalent collector design features and performance characteristics. The results of the product performance testing demonstrated equivalent performance to the predicate device performance and no new issues were raised.

Test Methods:

- **Puncture Resistance** (Performed by and independent materials testing lab) - Passed

- **Leak Resistance of bottom and sides** - Passed

- **Impact Resistance** - Passed
  Based on ISO 23907:2012

- **Stability** - Passed
Conclusion:

The performance testing summary demonstrates substantial equivalence between the BWCSH-1 Sharps Container and the predicate devices. BWCSH-1 Sharps Container has been tested by appropriate methods with respect to the relevant standards. FDA recognized ASTM standards F2132-01. No new issues of safety and effectiveness were raised with the testing performed and the BWCSH-1 Sharps Container is considered substantially equivalent to its predicate device.

*B.D Guardian™ Nestable Sharps Collector is a registered trademark of Becton Dickinson and Company.*
March 10, 2014

Bradford Wright Companies, Inc.
Mr. Mike DeMello
President
4092 Orchard Way
Lake Oswego, OR 97035

Re: K131708
Trade/Device Name: BWCSH-1 Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Sharps Container
Regulatory Class: II
Product Code: MMK
Dated: December 31, 2013
Received: January 28, 2014

Dear Mr. DeMello:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

The BWCSH-I sharps container has a one-gallon fill line capacity that is intended to be used for the safe disposal of hazardous sharps. The BWCSH-I sharps container is metallic canister fitted with thermal plastic top and has an orange-red biohazard label adhered to the containers with fill line printed on the front. The BWCSH-I device is for single use, disposable and is not a secondary container. BWCSH-I sharps container dimensions are 10.5 inches in width at the top, 4.75 inches deep and 8.25 inches in height. BWCSH-I sharps container weighs 1.075 pounds when empty.

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)

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Elizabeth F. Claverie-S
2014.03.09 09:33:57 - 04'00'

FORM FDA 3881 (9/13)