

510(k) SUMMARY

MAR 10 2014

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.
Organization Number: 338046
PIN: MD6068894-956733
SBD135362
4092 Orchard Way
Lake Oswego, OR 97035-1871
Phone/Fax: (503) 635-6908
Email: info@bradfordwright.com

Contact Person: Mike DeMello
President
Email: miked@bradfordwright.com

DEVICE IDENTIFICATION

510(k) Number: K131708
Device Name: BWCSH-1
Common Name: Sharps Container
Classification Name: MMK
Accessory to hypodermic single lumen needles
CFR Reference: 21CFR **880.5570- Class II**
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: MMK
 Accessory to hypodermic single lumen needles
 CFR Reference: 21CFR 880.5570- Class II
 Classification Panel: General Hospital

Legally Marketed Equivalent Devices:

Product	Company	510(k) #
Demolizer #47 1 Gallon Point of Generation Sharps Container	Thermal Waste Technologies, Inc.	K982781
B-D Guardian™ Nestable Sharps Collectors	Becton Dickinson & Co.	K 943575

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
- Stability - According to 29 CFR 1910.1030(d)(4)(iii)(A)(2)(ii).

General Specification Table

Product Description	Access opening size	Access opening and closure	Overall Size L x W x H (inches)	Weight (pounds)	Capacity at full line
BWCSH-1	9" x 1.75"	Rotating door and tamper resistant locking lid	10.5 x 4.75 x 8.25	1.075	1 Gallon

Table showing sharps container component dimensions:

Component	Material	Depth (inches)	Width (inches)	Height (inches)
Canister at Top	Tinplate Steel	4"	10 "	8 "
Canister Bottom	Tinplate Steel	3 "	9 "	N.A.
Sharps Chute closed	Molded Polypropylene	4 ³ / ₄ "	10 ¹ / ₂ "	2 ¹ / ₄ "
Sharps Chute alone	Molded Polypropylene	3 ³ / ₄ "	9 ¹ / ₂ "	2 "
Top Rim	Molded Polystyrene	4 ³ / ₄ "	10 ¹ / ₂ "	¹ / ₄ "
Lid Plug	Molded Polystyrene	3 ³ / ₄ "	9 ³ / ₄ "	³ / ₄ "
Sharps Container	Metal & Plastic	4 ³ / ₄ "	10 ¹ / ₂ "	8 ¹ / ₄ "

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:

Element of Comparison	Subject Device	Predicate Device #1	Predicate Device #2
Company	Bradford Wright Companies, Inc.	Thermal Waste Technologies, Inc.	Becton Dickinson & Co.
Device Name	BWCSH-1 Sharps Container	Demolizer # 47 One-Gallon Point of Generation Sharps Container	B-D Guardian™ Nestable Sharps Collectors
FDA 510(k) Number	K131708	K982781	K943575
Intended Use(s)	BWCSH-1 sharps container is intended to be used for the safe disposal of hazardous sharps.	Intended for the disposal of various-sized contaminated medical sharps (including needles, syringes, slides, and ampoules) in clinical and laboratory healthcare settings.	B-D sharps containers are intended to be used for the safe disposal of hazardous sharps
Target Population	Healthcare professional	Healthcare professional	Healthcare professional
Where Used	Healthcare Facilities	Intended for clinical, nonclinical healthcare settings such as laboratories, dentists' office, doctor's office, corporate clinics and nursing homes.	Healthcare Facilities
Material	Polypropylene, Polystyrene & Tinline steel	Tinline steel	Polypropylene
Sharps Access	Sharps inserted through the top	Sharps inserted through the top	Sharps inserted through the top
Sharps Closure	Lid is locked in place for removal	Closure feature is closed then locked	Flaps are closed and locked in place

		in place for removal	for removal
Impact Resistance	Yes	Not tested	Yes
Puncture Resistance	Yes	Yes	Yes
Leak Proof	Yes	Yes	Yes
Non-sterile	Yes	Yes	Yes
Single Use	Yes	Yes	Yes
Capable of maintaining a stable, upright position	Yes	Not tested	Yes
No features to bend, break, or shear needle.	No Feature Present	No Feature Present	No Feature Present
Reusable Sharps Containers	Labeling is "Single Use"	Labeling is "Single Use"	Labeling is "Single Use"
Overfill Indication	Labeled "Do Not Fill Above This Line"	Labeled "Do Not Fill Above This Line"	"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"
Clarity	Each Container has a minimum of one translucent component, either base or top	Temporary/Permanent Opening for visual inspection.	Each Collector has a minimum of one translucent component, either base or top
Construction	Injection Molded Lid and Rotating top and 2 piece seamed & glued tinplate base	3 piece seamed & glued tinplate	Injection Molded Containers, Lids and Closure
Dimensions	10.5 inches by 4.75 inches by 8.25 inches	6.5 inches in diameter by 8 inches	12 inches by 13.5 inches by 6 inches
Fill Capacity	One US gallon	One US gallon	7.6 Liters (2.01 US gallons)

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 6-215 identifies ASTM F2132-01 (reapproved 2008), "Standard Specifications for puncture Resistance of Materials Used for the Collection for Discarded Medical Needles and Other Sharps."

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

The performance testing demonstrates compliance with the recognized consensus standards, ASTM F2132-01 (reapproved 2008), "Standard Specifications for puncture Resistance of Materials Used for the Collection for Discarded Medical Needles and Other Sharps" and the applicable portions of 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**
ASTM F 2132-01 (2008) "Standard Specification for the Puncture Resistance of Materials used in containers for the Discarded Medical Needles and Other Sharps".

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.*



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 10, 2014

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

Re: K131708
Trade/Device Name: BWCSH-I 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" (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 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,

 Tejasni Purohit-Sheth, M.D.
Clinical Deputy Director
FOR

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

510(k) Number (if known)
K131708

Device Name
BWCSH-1 sharps container

Indications for Use (Describe)

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. 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

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

Elizabeth F. Claverie - S
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