



Food and Drug Administration
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December 4, 2014

Bellegrave Medical Supply, Inc.
Mr. Wayne Morse
President
8349 154th Avenue NE
Redmond, WA 98052

Re: K140285
Trade/Device Name: B Travel Savvy Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single-Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: November 6, 2014
Received: November 7, 2014

Dear Mr. Morse:

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.

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Enclosure

INDICATIONS FOR USE:

510(k) Number K140285

Device Name: B Travel Savvy Sharps Container

Indications for Use:

The B Travel Savvy Sharps Container intended use:

The Travel Savvy Sharps Container is a single-use device intended for disposal of sharps waste by a single user in a private site of use. When mounted with the appropriate bracket, the Travel Savvy Sharps Container can be used for sharps disposal in vehicles.

The B Travel Savvy Sharps container color is red. The length of the device is 6.5 inches, the width is 2.1 inches and the height is 2.3 inches. The aperture opening is 1.5 inches wide and the length is 2.5 inches.

Prescription Use _____

(Part 21 CFR 801 subpart D)

Over the counter use ___X___

(Part 21 CFR 801 subpart C)

K140285 510(k) Summary

B Travel Savvy Sharps Container

Date of Summary

November 26, 2014

1. Submitted by

Bellegrove Medical Supply, Inc.
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2. Contact information

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3. Device Identification:

Trade Name: B Travel Savvy Sharps Container
Common Name: Sharps Container
Classification: 21CFR 880.5570 – Class II
Product Code: MMK

4. Predicate devices:

Substantial equivalence is being claimed to the following legally marketed device:

Trade Name: BD Guardian™ Sharps Container
Common Name: Sharps Container
Classification: 21CFR 880.5570 – Class II
Product Code: MMK
Predicate 510k No K943134 Cleared 11/07/1994
CFR Reference: 21CFR 880.5570 – Class II
Classification Panel: General Hospital

5. Device Description

The B Travel Savvy Sharps Container is a single use device designed for the safe disposal of regulated medical waste such as contaminated sharps waste. The size of the container makes it

ideal for the safe disposal of medical waste in a private site of use. When mounted with the appropriate bracket, the Travel Savvy Sharps Container can be used for sharps disposal in vehicles.

All materials, including sides, bottom, and top are manufactured with Polypropylene plastic. The container is puncture resistant, leak proof on the sides and bottom and stable. Once the lid is closed the device cannot be opened.

A mounting bracket is provided for further security. The bracket is designed to secure the sharps container to a fixed location on a vehicle. No component or accessory has been received prior 510(k) clearance before this submission. There is only one model number being submitted with this 510(k).

This is a standalone device typically used by a passenger in a vehicle to dispose contaminated sharps waste. The user opens the lid, inserts the needle end of the syringe first into the container and then inserts the body of the syringe. The lid is then closed and locked. Informed staff checks to see if the sharps container has been used. If so, they make sure the lid is closed, disconnect it from the mounting bracket by pulling on the side. The used sharps container is disposed by trained personal.

The device model specification to this submission is listed below:

- Capacity - 0.35 quart
- Model number - BTS-702
- Part assembly
 - Top – p/n 701-13
 - Lid – p/n 701-15
 - Label – p/n 701-14
 - Bottom – p/n 701-16
 - Bracket – p/n 701-17
- Access opening – open top with restricted access opening with hinge lid that is a permanent closure
- Access opening size (in) – 1.5 wide by 2.5 length
- Length (in) – 6.5
- Width (in) – 2.1
- Height (in) – 2.3
- Weight (grams) – 72
- Device is formed by molding techniques
- Thickness of material – 2.36 mm
- Color – red
- Plastic CAS number – 9003-07-0
- Storage capacity – 10 3ml syringes, or 5 5ml syringes or 20 50 unit insulin syringes
- Manufacturer – Bellegrove Medical, 8349 154th Ave NE, Redmond, WA 98052

6. Intended Use:

The B Travel Savvy Sharps Container intended use:

The Travel Savvy Sharps Container is a single-use device intended for disposal of sharps waste by a single user in a private site of use. When mounted with the appropriate bracket, the Travel Savvy Sharps Container can be used for sharps disposal in vehicles.

7. Comparison to Predicate Devices:

Feature	B Travel Savvy Sharps Container	BD Guardian™ Sharps Container
K Number	K140285	K943134
Closable	Yes, snap fit lid/closure	Yes, snap fit cap/closure
Puncture resistant	Yes	Yes
Leak proof on sides and bottom	Same	Yes
Labeled or color coded:	Same	Sharps disposal
Biohazard warning	Same	Yes
Fluorescent orange or orange-red with lettering in contrasting colors	Same	Yes
Affixed to container	Same	Yes
Red container or label	Same	Yes
Capable of maintaining stable, upright position	Same	Yes
No features to bend, break, or shear needle.	Same	No feature present
Unwinder	Feature not available	Yes
Reusable sharp container	Same	Labeling is "Single Use Only"
Overfill indication	Same	"do not overfill" or "fill to this level only"
Materials	Same	Polypropylene
Construction	Same	Injection molded container Injection molded lids/closures
Holder	Bracket to mount on flat surface	Capable of attaching to wall-mount or cart-mount
Locking Enclosure	Not provided	Yes

8. Discussion of similarities and differences in new and predicate product

Intended use comparison

The indications for use of the new B Travel Savvy sharps container are similar to the predicate devices in that they are intended for the disposal of contaminated medical waste. Both devices have a lid that once in place it cannot be removed.

Design and materials comparison

The design and functionality of the sharps containers and predicate devices are similar. They are constructed from polypropylene and are intended for single use only. Both devices conform to recognized standard, ASTM F-2131-01 for needle penetration resistance. They have features to prevent contact between user and the contents, and are designed for easy and safe determination of fullness. The B Travel Savvy sharps container includes a bracket.

9. Summary of performance bench testing

9.1. Performance standards:

No performance standards have been established under section 514 for this product code. All recognized standards and other regulations and guidance documents that were used in this 510(k) have been listed.

The performance testing demonstrates compliance with the recognized consensus standard, ASTM F-2132-01 (reapproved 2008) el, "Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps." In addition the relevant FDA guidance document, "Guidance on the Content and Format of Premarket Notification [510(K)] Submission for Sharps Containers" dated October 1993, was used to identify applicable physical and mechanical features of the modified and predicate devices.

All applicable standards have been used to show that the B Travel Savvy container is substantially equivalent to the listed predicate device.

The performance testing summary demonstrates substantial equivalence between the modified device and the predicate device. The new sharp container has been tested by appropriate methods with respect to relevant FDA guidance documents; FDA recognized ASTM standards F 2132-01 and OSHA regulations 29 CFR Part 1910:1030. No new issues of safety and effectiveness were raised with the testing performed, and the B Travel Savvy container is considered substantially equivalent to it predicate device.

9.2. Performance testing (bench) – product testing

The results of product performance testing demonstrated equivalent performance to predicate device performance and no new issues of concern were raised.

9.2.1. Impact and leak resistance

Impact resistance was assessed such that no open fractures or disassembly results when a filled container is dropped. The container is filled with assorted sharps or syringes with or without needles, or equivalent weight using resin beads and sealed as if ready for transport.

Results: The sharps container passed the impact and leak resistance tests.

9.2.2. Needle penetration resistance

Needle penetration resistance is based on ASTM F-2131-01, "Standard Specification for penetration resistance of materials used in containers for discarded medical needles and other sharps", for minimum and average needle penetration force. The test method involves cutting samples from the needle containment area of the sharps container. Each sample is tested using a motorized mechanical tester (Isntron, ATS or equivalent with a new 21 gauge x 1" needle, each penetration is tested at 4"/minute.

Results: All 12 needle puncture force tests were greater the minimum requirement of 2.8 lbf and average of puncture force of 3.4 lbf. The sharps container passed the needle penetration resistance tests.

9.2.3. Leak resistance

The leak resistance testing is based on OSHA specification (29 CFR 1910.1030). The container is filled with water to the labeled fill line and left to stand on its base 1 hour.

Results: The container passed this test. No leaks were observed with product standing in upright position.

9.2.4. Sharps access and closure

The sharps access and closure test is designed the functionality of the device. A sharps container is filled with various sized syringes to the fill line. Close the lid. Subject the container to normal opening and closing processes for 100 times. Each time check to validate each syringe is below the full line. Repeat the impact and leak test.

Results: The sharps container passed. There were no wear or tear of the device after the 100 tests opening and closing of the device.

9.2.5. Stability – spillage of sharps waste

Fill it with 1 oz. of water and various sizes of syringes to the fill line. Position the sharps container about 3 feet above the floor. Release the container. Examine the sharps container for integrity and evidence of leakage/wetting of the outer surface of the container and /or wetting of the impact surface. Repeat the procedure in a different orientation (base, side wall, adjacent side wall and top using a new container for each test.

Results: The tested devices did not leak and there was not a breach of the sharps. The containers passed this test.

9.2.6. Handling - transit damage resistance/stacking test

Transit damage testing demonstrates the product is free from any visible damage that may affect customer usage, safety, or satisfaction when products are packaged in shipping cases and dropped. The appropriate number of products are packaged in the appropriate shipping case and sealed as if ready for shipment. The shipping case is dropped from 24" onto a hard surface floor in 10 different orientations.

Results: The sharps container passed. The sharps container was free from any visible damage that may affect customer usage, safety, or satisfaction when products are packaged in the shipping case and dropped. The sharps container passed the transit damage resistance test. The sharps container was free from any visible damage that may affect customer usage, safety, or satisfaction when products are packaged in the shipping case. The sharps container passed the stacking test.

9.2.7. Conclusion

Based on the performance test results, the subject device is as safe and effective as the predicate device and is substantially equivalent to the predicate device.