May 20, 2019

Bluestone Medical, Inc.
Jon Bricken
President
(DBA OnSite Waste Technologies, Inc.)
9 North Main Street
East Hampton, New York 11937

Re: K182235
Trade/Device Name: OnSite Waste Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: March 26, 2019
Received: April 15, 2019

Dear Jon Bricken:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For David Krause, PhD
Acting Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182235

Device Name
OnSite Waste Sharps Container

Indications for Use *(Describe)*
Bluestone Medical, Inc. OWTSH-I Sharps Container is a single- use, disposable, non-sterile container intended to be used for health-care purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target population is for qualified personnel in health care facilities and in other facilities in which medical sharps may be used. The container is intended to be used in areas where there is no unsupervised patient access.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Bluestone Medical, Inc.
9 North Main Street, suite #7
East Hampton, N.Y. 11937

510(k) Summary

The assigned 510(k) number is: K182235

1. Date Prepared: May 14, 2019

2. Submitter's Identification

   Bluestone Medical, Inc

   Address: 9 North Main Street, suite #7 East Hampton, N.Y. 11937

   Contact person: Jon Bricken President

   (914)-886-3958

   Email: jon.bricken@onsitewaste.com

3. Name of the Device

   Device Name: Sharps Container

   Trade Name: OnSiteWaste Sharps Container

   FDA identification: OWTSH-I

4. Classification Information:

   Product Code: MMK

   Device Class: Class II

   Classification: assessors to hypodermic single lumen needles

   Classification Panel: General Hospital

5. Predicate Device Information:

   Trade name: Bradford Wright Sharps Container

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Common name: Sharps Container

Product code: MMK

Classification: Accessory to hypodermic single lumen needles

CFR Reference: 21CFR880.5570-Class II

Classification: panel: General Hospital

Legally Marketed Predicate Device:

Company	Product description	510(k) #
Bradford Wright Companies, Inc.	Demolizer II Sharps Container	K131708 (Primary Predicate)

6. Intended use / Indication for Use:

Bluestone Medical, Inc. OWTSH-I Sharps Container is a single- use, disposable, non-sterile container intended to be used for health-care purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target population is for qualified personnel in health care facilities and in other facilities in which medical sharps may be used. The container is intended to be used in areas where there is no unsupervised patient access.

7. Device Description:

The OnSite Waste Sharps Container OWTSH-I is constructed using tinplate steel base with a Nylon and polypropylene restrictive lid system. The OnSite Waste Sharps Container OWTSH-I measures 10 1/2“ wide x 4 3/4” deep, and tapers to a dimension of 9” wide x 3 1/8 deep. The height of the container is 8 1/4” in height. The OnSite Waste Sharps Container OWTSH-I is equipped with a locking lid that once closed, prevents anyone from opening it either before or after processing.

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Labels are on a red background with printed in black text and a bio-hazzard symbol. Labels are adhered to the container at the time of manufacture with the fill line warning printed on the label There is no feature to bend, break, or shear needle, includes blunting of needle in container.

OnSite Waste Sharps Container OWTSH-I

Component	Material	Depth (inches)	Width (inches)	Height (inches)
Container at Top	Tinplate Steel	4"	10"	8"
Container at 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 Polypropylene	4 3/4"	10 1/2"	1/4"
Lid Plug	Molded Polypropylene	3 3/4"	9 1/4"	3/4"
Sharps Container	Metal & Plastic	4 3/4"	10 1/2"	8 1/4"

8. Technological Characteristics

Element of Comparison	Subject Device	Predicate Device
Company	Bluestone Medical, Inc.	Bradford Wright Companies, Inc.
Device Name	OWTSH-I Sharps Container	BWCSH-i Sharps Container
FDA 510(k) Number	K182235	K131708
Intended Uses	Container is a single- use, disposable, non-sterile container intended to be used for health-care purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles.	sharps container has a one-gallon fill line capacity that is intended to be used for the safe disposal of hazardous sharps.
Target Population	Healthcare Professionals	Healthcare Professionals
Materials	Tin Plate & Plastic	Tin Plate & Plastic

Element of Comparison	Subject Device	Predicate Device
Sharps Access	Sharps inserted through the top	Sharps inserted through the top
Sharps Closure	Lid locked in place	Lid locked in place
Impact Resistance	Yes	Yes
Puncture Resistance	Yes	Yes
Leak Proof	Yes	Yes
Non-Sterile	Yes	Yes
Single Use	Yes	Yes
No features to bend, break or shear needle	No Features Present	No Features Present
Fill indications	Labeled "Do Not Fill Above This Line"	Labeled "Do Not Fill Above This Line"
Construction	Injection molded lid and Tin Plate base	Injection molded lid and Tin Plate base
Dimensions	10.5"x4.75"x8.25"	10.5"x4.75"x8.25"
Fill Capacity	One US Gallon	One Us Gallon

9. Summary of Non-Clinical Testing

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 - Container is filled with water. No Leakage visually observed after 24 hour period - Passed.

Impact Resistance - Passed Based on ISO 23907:2012

Stability: - Passed Based on ISO 23907:2012

10. Discussion of Clinical Tests Performed:
There were no clinical testing required to support the medical device.

11. Conclusions:
The results of the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device