DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 9, 2016

Oak Ridge Products, LLC
C/O Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K161180
Trade/Device Name: Oak Ridge Products Sharps Containers
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: MMK
Dated: May 23, 2016
Received: May 26, 2016

Dear Mr. Job:

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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
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: January 31, 2017
See *PRA Statement below.*

51O(k) Number *(if known)* K161180

Device Name
Oak Ridge Products Sharps Containers

Indications for Use *(Describe)*

Oak Ridge Products Sharps containers are a single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target population is for trained healthcare professionals. All the containers are intended to be used in areas where there is no unsupervised patient access.

Oak Ridge Part Number	**Product Description and closure type**	**Access opening size**	**Overall Size L x W x H**	**Weight (grams) empty**	**Total Capacity**	**Capacity at full line**	**Mounting**
0322-150R	2.2 quart Sharps container – rotary door	3.4 x 1.5 inches	6.25 x 4.6 x 6.7 Inches	172 grams	2.3 quarts	1.8 quarts	Free Standing or Holder
0319-1500	1 gallon Sharps container– sliding door	5.6 x 2.3 inches	10.3 x 7.0 x 5.5 inches	280 grams	4.8 quarts	3.4 quarts	Free Standing
0319-150R	1 gallon Sharps container– Rotary Door	4 x 1.75 inches	10.3 x 7.0 x 5.5 inches	280 grams	4.8 quarts	3.4 quarts	Free Standing
0319-150F	1 gallon Sharps container– Folding Door	8.2 x 2.1 inches	10.3 x 7.0 x 5.5 inches	310 grams	4.8 quarts	3.4 quarts	Free Standing
0320-150R	2 gallon Sharps container – w/ Rotary door	4 x 1.75 inches	10.3 x 7.0 x 10.1 inches	367 grams	7.8 quarts	6 quarts	Free Standing
0320-150F	2 gallon Sharps container – w/ folding door	8.2 x 2.1 inches	10.3 x 7.0 x 10.1 inches	397 grams	7.8 quarts	6 quarts	Free Standing

Type of Use *(Select one or both, as applicable)*

[ ] Prescription Use (Part 21 CFR 801 Subpart D) [X] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Summary Preparation Date: June 8, 2016

1. Submitted By

Oak Ridge Products L.L.C.
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McHenry, Illinois, 60050 USA
Establishment Registration #:1419823

2. Contact Information (Primary)

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(815) 363-4700

3. Device identification:

Trade Name:	Oak Ridge Products Sharps Container
Common Name:	Sharps Container
Product Code:	MMK
Classification:	Accessory to hypodermic single lumen needles
CFR Reference:	21 CFR 880.5570 – Class II
Classification Panel:	General Hospital

4. Predicate devices:

Trade Name:	Oak Ridge Products - Sharps Container
Common Name:	Sharps Container
Product Code:	MMK
Classification:	Accessory to hypodermic single lumen needles
CFR Reference:	21 CFR 880.5570 – Class II
Classification Panel:	General Hospital

Legally Marketed Equivalent Device:

Company	Product	510(k)#
Oak Ridge Products	1 quart Phlebotomy Sharps Container	K130281
Oak Ridge Products	2 Gallon Sharps Container	K130281

5. Product Description:

The Oak Ridge Products Sharps Containers are of injection molded polypropylene plastic, designed for a single-use by healthcare professionals. No part of the container is intended to come in contact with patients. The containers are designed to be puncture resistant, leak resistant on the sides and bottom, impact resistant, closable and stable. Large access openings allow for disposal of sharps with one hand use. The plastic used for the sharps containers are of a similar chemical formula as the comparable predicate devices and many of the sharps objects that will be placed within the container such as plastic syringe bodies. These containers are suitable for a terminal disposal by incineration and all materials used are fully consumable during incineration.

The Oak Ridge Products Sharps Containers are made of three parts (a base, a lid, and a closure) that form a single unit. The lid and closure come preassembled with the base not attached. Parts are nested to together to reduce storage and shipping requirements. The healthcare facility performs the final assembly on-site by snapping the lid to the base.

Lids and closures are uncolored translucent material allowing for a visual determination of fill level. The base is made from a high strength material to support the capacity of the container. The recommended fill level is engraved onto the plastic and corresponds to the fill level line on the product identification label.

General Specifications:

Sharps containers							
Oak Ridge Part Number	**Product Description and closure type**	**Access opening size**	**Overall Size L x W x H**	**Weight (grams) empty**	**Total Capacity**	**Capacity at full line**	**Mounting**
0322-150R	2.2 quart Sharps container – rotary door	3.4 x 1.5 inches	6.25 x 4.6 x 6.7 Inches	172 grams	2.3 quarts	1.8 quarts	Free Standing or holder
0319-1500	1 gallon Sharps container– sliding door	5.6 x 2.3 inches	10.3 x 7.0 x 5.5 inches	280 grams	4.8 quarts	3.4 quarts	Free Standing
0319-150R	1 gallon Sharps container– rotary door	4 x 1.75 inches	10.3 x 7.0 x 5.5 inches	280 grams	4.8 quarts	3.4 quarts	Free Standing
0319-150F	1 gallon Sharps container– folding door	8.2 x 2.1 inches	10.3 x 7.0 x 5.5 inches	310 grams	4.8 quarts	3.4 quarts	Free Standing
0320-150R	2 gallon Sharps container – w/ rotary door	4 x 1.75 inches	10.3 x 7.0 x 10.1 inches	367 grams	7.8 quarts	6 quarts	Free Standing
0320-150F	2 gallon Sharps container – w/ folding door	8.2 x 2.1 inches	10.3 x 7.0 x 10.1 inches	397 grams	7.8 quarts	6 quarts	Free Standing

The 2.2 quart sharps container utilizes a semi-circular closure that is 4” in diameter. The closure is manually operated by the user. The closure has two finger tabs that allow operation of the closure while keeping fingers above the open access area of the sharps container. In the open position the needle unwinder feature is accessible. Use of this feature is described below (unwinder feature). When not in use the closure is rotated to a temporary closed position. In this position the device opening is fully covered preventing any sharps objects from being accessed. The top of the lid and closure have embossed arrows and text ‘ALIGN ARROWS TO LOCK’. For the final lock the user rotates the closure aligning the arrows. When aligned there is an audible ‘Snap’, the closure cannot be rotated any further and cannot be reopened.

Needle unwinder feature
The unwinder feature on the 2.2 quart container is located on the lid under the rotating closure and above the containment area. The unwinder has a round entry port for the needle to pass thru, allowing it to be fully enclosed within the container. Once the needle is inserted into the round port the Luer end of the needle is guided into the tapered slot which secures the needle body allowing for the syringe to be rotated and detached from the needle. The needle is unscrewed from the syringe body allowing it to drop into the sharps container without the need to be touch or handled. The sharps container allows for one-hand usage and complies with the OSHA Compliance Directive on needle unwinders as stated in the FDA guidance document, "Guidance on the Content and Format of Premarket Notification [510(k)] Submission for Sharps Collectors dated October 1993".
When using the needle unwinder feature, the table top mounting bracket Oak Ridge part 1222-010N is required.

The 1 gallon capacity container is offered in three lid configurations. All three use the same base unit, only the lids and closures are changed. The model 0319-1500 has a sliding closure, suitable for a vertical or horizontal drop of sharps devices. This model uses the same lid and closure as the predicate device Oak Ridge 2 gallon sharps container PN 0320-1500.

The model 0319-150R has a rotating closure suitable for a vertical dropping. This functions the same as the 2.2 quart described above with the closure being larger (4.5" diameter) a needle unwinder feature is not present on this model.

The model 0319-150F is a horizontal drop for larger sharps devices. This uses a fold down closure which is preassembled at the time of manufacture. All the areas that bend or fold during usage are protected from the sharps contents by the full material thickness of the lid. At no time during the containers use or disposal are these areas exposed to the sharps devices. The closure has temporary snaps that keep the closure in the closed position between uses. For final locking two additional locking tabs on the closure are snapped into the lid. Once locked the container cannot be reopened.

The two new 2 gallon sharps containers 0320-150R and 0320-150F utilize the same base as its predicate 2 gallon sharps container 0320-1500. The lid and closures being used are the same ones described for the 1 gallon sharps containers above. An unwinder feature is not available on the 1 gallon and 2 gallon sharps containers.

The Oak Ridge Products Sharps Containers conform to the recognized standard ASTM F2132-01(2008) for needle puncture resistance. These also meet or exceed the OSHA 1910.1030 recommendations for sharps containers.

6. Indications for Use:

Oak Ridge Products Sharps containers are a single-use, disposable, non-sterile containers intended to be used for healthcare purposes for safe disposal of hazardous sharps such as hypodermic needles, syringes, lancets and blood needles. The target population is for trained healthcare professionals.

All the containers are intended to be used in areas where there is no unsupervised patient access.

Sharps containers							
Oak Ridge Part Number	**Product Description and closure type**	**Access opening size**	**Overall Size L x W x H**	**Weight (grams) empty**	**Total Capacity**	**Capacity at full line**	**Mounting**
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0319-1500	1 gallon Sharps container– sliding door	5.6 x 2.3 inches	10.3 x 7.0 x 5.5 inches	280 grams	4.8 quarts	3.4 quarts	Free Standing
0319-150R	1 gallon Sharps container– rotary door	4 x 1.75 inches	10.3 x 7.0 x 5.5 inches	280 grams	4.8 quarts	3.4 quarts	Free Standing
0319-150F	1 gallon Sharps container– folding door	8.2 x 2.1 inches	10.3 x 7.0 x 5.5 inches	310 grams	4.8 quarts	3.4 quarts	Free Standing
0320-150R	2 gallon Sharps container – w/ rotary door	4 x 1.75 inches	10.3 x 7.0 x 10.1 inches	367 grams	7.8 quarts	6 quarts	Free Standing
0320-150F	2 gallon Sharps container – w/ folding door	8.2 x 2.1 inches	10.3 x 7.0 x 10.1 inches	397 grams	7.8 quarts	6 quarts	Free Standing

7. Comparison to Predicate Devices:

Manufacturer	**Oak Ridge Products** (New Devices)	**Oak Ridge Products** (Predicate Device)
Trade Name	Oak Ridge Products Sharps Containers	Oak Ridge Products Sharps Containers
510(k) number	K161180	K130281
Indication for use	Oak Ridge sharps containers are intended to be used for the safe disposal of hazardous sharps	Oak Ridge sharps containers are intended to be used for the safe disposal of hazardous sharps
Target Population	Healthcare professional	Healthcare professional
Where used	Healthcare facilities	Healthcare facilities
Material	Polypropylene	Polypropylene
Sharps access	Sharps inserted through the top	Sharps inserted through the top
Sharps closure	Closure feature is closed then locked in place for removal	Closure feature is closed then locked in place for removal
Impact resistance	Yes	Yes
Puncture resistance	Yes	Yes
Leak resistance	Yes	Yes
Single use	Yes	Yes
Non-sterile	Yes	Yes
Capable of maintaining a stable, upright position	Yes	Yes
No features to bend, break, or shear needle.	No Feature Present	No Feature Present
Reusable Sharps Containers	Same	Labeling is “Single Use Only”

Overfill Indication	Same	"Do Not Overfill" or "Fill to this Level Only" is Labeled or embossed on the container at the location of the full point. Labeling includes a "Fill Line".
Clarity	Same	Each Collector has a minimum of one translucent component, either base or top.
Construction	Same	Injection Molded Containers, Lids and Closure
Unwinder	Feature present only on 2.2 quart container	1 quart Phlebotomy container has this feature.

8. Substantial Equivalence Discussion of Similarities and Differences:

The Oak Ridge Products Sharps Containers are similar to the Oak Ridge Products Sharps Containers in:

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

9. Intended use comparison:

The intended use of the new Oak Ridge Products Sharps Container is the same as the predicate device. Oak Ridge Products Sharp Containers are containers intended for the disposal of contaminated sharps waste in a healthcare facility.

10. Design and Material Comparison:

The design and functional characteristics of the Oak Ridge Products Sharps Containers and the predicate device are similar. The Oak Ridge Products Sharps Container parts are nestable and when assembled form a single unit. These units have features to prevent contact between user and the contents and are designed for a visual determination of the maximum capacity. None of the devices have features that bend, break, or shear needles. The devices are designed for a single use by a locking feature in the lid and closure.

They are constructed of an injection molded polypropylene. Oak Ridge Products Sharps Containers are colored red with translucent lid that allows for a visual determination of content level.

11. Summary of Non-Clinical Performance Bench Testing:

11.1 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."
- 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 Oak Ridge Products sharps containers and the predicate device.

All applicable standards have been used to show that the Oak Ridge Products Sharps Container is substantially equivalent to the appropriately listed predicate device.

11.2 Performance Testing (Bench) – Product Testing

The Oak Ridge Products Sharps Containers incorporate 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 an 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
Based on OSHA Specification 29CFR 1910:1030

Overfill detection and Capacity: – Passed

Needle unwinder: - only present on the 2.2 quart model - Passed

Impact resistance and safe handling – Passed
Based on ISO 23907:2012

Sharps access, closure: – Passed

Stability: – Passed
Based on ISO 23907:2012

Mounting Brackets usability and stability: – Passed:
Applies only to the 2.2 quart sharps container. The 1 gallon and 2 gallon containers are free standing devices.
Based on ISO 23907:2012

11.3 Performance test summary:

The performance testing summary demonstrates substantial equivalence between the Oak Ridge Products device and the predicate devices. The Oak Ridge Products Sharps containers have been tested by appropriate methods with respect to the relevant standards, FDA recognized ASTM standards F 2132-01, OSHA regulations 29 CFR Part 1910:1030 and ISO 23907:2012(e). No new issues were raised with the testing performed, and the Oak Ridge Products Sharps containers are considered substantially equivalent to its predicate device.

12. Conclusion:

The Oak Ridge Products Sharps Containers introduces no new questions. From the testing performed the new devices are as safe, as effective and performs as well as the predicate device. Oak Ridge Products concludes that the devices are substantially equivalent to the respective predicate sharps collectors.