DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 26, 2016

Triumvirate Environmental, Inc.
% Allison C. Komiyama, Ph.D., R.A.C.
Representative/Consultant
AcKnowledge Regulatory Strategies
2834 Hawthorn St.
San Diego, CA 92104

Re: K153363
Trade/Device Name: Red2Green Reusable Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: June 23, 2016
Received: June 24, 2016

Dear Dr. Komiyama:

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" (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 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

Tina Kiang, Ph.D.
Acting 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.

510(k) Number *(if known)*
K153363

Device Name
Red2Green Reusable Sharps Container

Indications for Use *(Describe)*
Red2Green Reusable Sharps Containers and accessories are intended to be used in healthcare facilities including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian offices and other small quantity waste generators for the safe disposal, storage and transportation of hazardous sharps.

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)*

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

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510(k) Summary
K153363

DATE PREPARED
July 26, 2016

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PROPRIETARY NAME OF SUBJECT DEVICE
Red2Green Reusable Sharps Container

COMMON NAME
Container, Sharps

DEVICE CLASSIFICATION
Hypodermic single lumen needle
(21 CFR 880.5570, Product Code MMK, Class II)

PREMARKET REVIEW
ODE/DAGRID/INCB
General Hospital Panel

510(k) Summary

INDICATIONS FOR USE

Red2Green Reusable Sharps Containers and accessories are intended to be used in healthcare facilities including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian offices and other small quantity waste generators for the safe disposal, storage and transportation of hazardous sharps.

DEVICE DESCRIPTION

Red2Green Reusable Sharps Containers are reusable sharps containers designed for disposal of sharps. The containers are intended for over-the-counter use for the safe disposal of sharps, i.e. articles that can penetrate human skin. This definition includes, but is not limited to needles, scalpels, syringes with needles, disposable scissors, suture needles, stylets, trocars and broken test tubes. Device configurations are as follows:

Part #	Part Name	Associated Lids	Aperture Dimensions	Optional Accessories
2-001	2 Gallon Container Body (Red) 6.3” x 12.8” x 10.4”	2-002 Vertical Drop Lid 2-003 Horizontal Drop Lid	2.25” ϕ 1.75” x 9.375”	2-004 Wall Enclosure 2-006 Metal Wall Bracket 2-005 Stabilizer
3-001	3 Gallon Container Body (Red) 6.3” x 12.8” x 15.3”	2-002 Vertical Drop Lid 2-003 Horizontal Drop Lid	2.25” ϕ 1.75” x 9.375”	3-002 Wall Enclosure 2-006 Metal Wall Bracket 2-005 Stabilizer
4-001	4 Gallon Container Body (Red) 6.3” x 12.8” x 20.1”	2-002 Vertical Drop Lid 2-003 Horizontal Drop Lid	2.25” ϕ 1.75” x 9.375”	4-002 Wall Enclosure 2-006 Metal Wall Bracket 2-005 Stabilizer
8-001	8 Gallon Container Body (Red) 13” x 13” x 17.4”	8-002 Vertical Drop Lid 8-003 Gallon Lab Lid*	2.25” ϕ 6.5” x 7”	8-004 Stabilizer 8-005 Basic Rolling Dolly 8-006 Foot Pedal Dolly
8-007	8 Gallon Container Body (Yellow) 13” x 13” x 17.4”	8-002 Vertical Drop Lid 8-003 Gallon Lab Lid*	2.25” ϕ 6.5” x 7”	8-004 Stabilizer 8-005 Basic Rolling Dolly 8-006 Foot Pedal Dolly
10-001	10 Gallon Container Body (Red) 13” x 13” x 22.3”	8-002 Vertical Drop Lid 8-003 Gallon Lab Lid*	2.25” ϕ 6.5” x 7”	8-004 Stabilizer 8-005 Basic Rolling Dolly 10-002 Foot Pedal Dolly
10-003	10 Gallon Container Body (Yellow) 13” x 13” x 22.3”	8-002 Vertical Drop Lid 8-003 Gallon Lab Lid*	2.25” ϕ 6.5” x 7”	8-004 Stabilizer 8-005 Basic Rolling Dolly 10-002 Foot Pedal Dolly
17-001	17 Gallon Container Body (Red) 13” x 17” x 24.7”	17-002 Transportation Lid*	13” x 17”	17-003 Basic Rolling Dolly 17-004 Foot Pedal Dolly
17-005	17 Gallon Container Body (Yellow) 13” x 17” x 24.7”	17-002 Transportation Lid*	13” x 17”	17-003 Basic Rolling Dolly 17-004 Foot Pedal Dolly

* For commercial or healthcare users: for use only in areas with no unsupervised patient/customer access.

510(k) Summary

PREDICATE DEVICE IDENTIFICATION

The Red2Green Reusable Sharps Container is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K132007	Stericycle Sharps Management Service Reusable Sharps Container / Stericycle, Inc.	✓
K950897	Biobox TrapTop / Biosystems	
K950898	Biobox with Funnel Top / Biosystems	

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the Red2Green Reusable Sharps Container. The following tests were performed to demonstrate safety based on current industry standards and predetermined acceptance criteria.

Puncture resistance (per ASTM F2132): This test was performed by selecting sections from each area of the container or lid and subjecting them to a 21 gage needle advancing at a rate of 4”/min. Per the acceptance criteria, the average puncture force was no less than 3.4 lbf with no one value from any region being less than 2.8 lbf. All containers and lids were tested.

Impact with Leak test (per ISO 23907): Containers were filled with representative sharps material and 1% volume of water. The lid was closed and the container was placed 1 m from the impact surface. The container was allowed to free fall and land on its base, side wall, and adjacent side wall. Additionally, the 2 and 3 gallon containers were allowed to free fall and land on their lids as specified in the standard. Per the acceptance criteria, there was no loss of container integrity and no evidence of leakage. All containers and lids were tested in each possible configuration.

Stability test (per ISO 23907): One container was filled with representative sharps material and placed on a surface with a 15° incline. The container lid was left open and was tested in both orientations. Per the acceptance criteria, the device did not topple.

Impact test (per 49 CFR 178.603): Five containers were filled with representative sharps material to a gross mass of 50 lbs and conditioned at 0° F for at least 24 hours. The container was allowed to free fall from a height of 1.2 m and land on its base, top, side wall, adjacent side wall, and bottom corner. Per the acceptance criteria, there was no damage to the outer packaging and no leakage of the filling substance.

Stacking test (per 49 CFR 178.606): Five containers were filled with representative sharps material to a gross mass of 50 lbs and then subjected to a static load of 250 lbs. Per the acceptance criteria, the load was sustained for 24 hours at a temperature of 23° C and 50% relative humidity. No damage, leakage or deterioration that could adversely affect transportation safety was observed.

Vibration test (per 49 CFR 178.608): Three containers were filled with representative sharps material to a gross mass of 50 lbs and then subjected to vibration at 278 cpm for 1 hour. Per the acceptance criteria, there was no damage to the outer packaging and no leakage of the filling substance.

Accessory strength test: The strength of Wall Enclosures and Metal Wall Bracket were tested by filling their associated sharps container with water. The filled container was placed into one of each of the respective wall mounted accessories. After 48 hours the containers were removed and the accessories were inspected for any loss of integrity. There was no evidence of sagging, breakage, liquid leakage, or changes in performance for the locking mechanisms.

Repeated opening test: To demonstrate that repeated opening and closing of the device does not negatively affect performance, three samples of the Horizontal Drop Lid were manually opened and closed for 1000 repetitions. The device was inspected for any damage or loss of functionality to the container or lid. For all three samples, the device remained undamaged and there were no signs of malfunction of the lid.

Life cycle test: Five representative sharps containers were filled with representative sharps material, tipped, dumped, disinfected, washed, dried and processed 400 times. There was no evidence of discoloration, cracks, breaks or other deficiencies (such as deterioration to the label) that would prevent the containers from operating normally. After 400 cycles, the devices were subjected to vibration simulation per ISTA Procedure 3E, one round of leak testing, impact testing per 49 CFR 178.603, and then a second round of leak testing. One sharps container was then subjected to puncture resistance testing per ASTM F2132. After reprocessing, the integrity of the device endured, and no changes to the performance or technical characteristics were visible.

EQUIVALENCE TO PREDICATE DEVICES

The subject device has a similar design and dimensions, and uses similar or identical materials as the devices cleared in K132007, K950897, and K950898. The colors and lid configurations are similar to those cleared in K132007. The subject device has the same intended use and similar technological characteristics (i.e. the lid closure) to the devices cleared in K132007, K950897, and K950898. The device has similar accessories to the devices cleared in K950897, and K950898.

510(k) Summary

Triumvirate Environmental, Inc. believes that the Red2Green Reusable Sharps Container is substantially equivalent to the predicate devices based on the information summarized in the table below.

	Subject Device	***Predicate Device***		
	Triumvirate Environmental, Inc. Red2Green Reusable Sharps Container K153363	Stericycle, Inc. Stericycle Sharps Management Service Reusable Sharps Container K132007	Biosystems Biobox TrapTop (Small, Medium, Large and X-Large) K950897	Biosystems Biobox with Funnel Top (Small, Medium, Large and X-Large) K950898
Indications for Use	Red2Green Reusable Sharps Containers and accessories are intended to be used in healthcare facilities including nursing stations, medication carts, laboratories, dental offices, emergency rooms, surgical rooms, treatment rooms, emergency vehicles, veterinarian offices and other small quantity waste generators for the safe disposal, storage and transportation of hazardous sharps.	The Stericycle Sharps Management Service Reusable Sharps Container is intended for use in health care facilities for the storage and transport for disposal of syringes and other medical sharps waste.	Unknown	Unknown
Device Design	Reusable containers designed for the safe disposal of sharps, i.e. articles that can penetrate human skin. The base of the container is rectangular in shape. Different base dimensions and various lid designs are available based on the amount and type of waste that is generated in a specific healthcare location.	Reusable containers designed for the safe disposal of sharps, i.e. articles that can penetrate human skin. The base of the container is rectangular in shape. Different base dimensions and various lid designs are available based on the amount and type of waste that is generated in a specific healthcare location.	Containers designed for the safe disposal of sharps, i.e. articles that can penetrate human skin. The base of the container is rectangular in shape. Different base dimensions and various lid designs are available based on the amount and type of waste that is generated in a specific healthcare location.	Containers designed for the safe disposal of sharps, i.e. articles that can penetrate human skin. The base of the container is rectangular in shape. Different base dimensions and various lid designs are available based on the amount and type of waste that is generated in a specific healthcare location.

	Subject Device	***Predicate Device***		
ProCodes / Reg #	MMK / 21 CFR 880.5570	MMK / 21 CFR 880.5570	MMK / 21 CFR 880.5570	MMK / 21 CFR 880.5570
Model Types	2 gallon 3 gallon 4 gallon 8 gallon 10 gallon 17 gallon	2 gallon 4 gallon	8 gallon 17 gallon	8 gallon 17 gallon
Physical Properties				
Material	Medium density polyethylene	Polypropylene copolymer	Polypropylene copolymer	Polypropylene copolymer
Color	Red or yellow	Red or yellow	Red	Red
Dimensions **L x W x H (inches)**	2 gallon: 6.3 x 12.8 x 10.4 3 gallon: 6.3 x 12.8 x 15.3 4 gallon: 6.3 x 12.8 x 20.1 8 gallon: 13 x 13 x 17.4 10 gallon: 13 x 13 x 22.3 17 gallon: 13 x 17 x 24.7	2 gallon: 6.9 x 12.3 x 13.9 4 gallon: 6.9 x 12.3 x 21.9	8 gallon: 11.3 x 13 x 19.7 17 gallon: 13.3 x 17.5 x 24.8	8 gallon: 11.3 x 13 x 19.7 17 gallon: 13.3 x 17.5 x 24.8
Container Closure	Vertical and horizontal drop, lab lid, transportation lid	Vertical and horizontal drop	Horizontal drop, lab lid, transportation lid	Vertical drop, lab lid, transportation lid
Technological Properties				
Reusable or Single-use Container	Reusable	Reusable	Unknown	Unknown
Accessories	Stabilizing tray, wall enclosure, wall bracket, rolling dolly, foot pedal dolly	Unknown	Stabilizing tray, wall enclosure, wall bracket, rolling dolly, foot pedal dolly	Stabilizing tray, wall enclosure, wall bracket, rolling dolly, foot pedal dolly
Needle Removal Mechanism	No	No	No	No
Non-Clinical Testing				
Performance testing	• Puncture resistance • Impact w/ leak • Stability • Impact • Stacking • Vibration • Accessory strength • Repeated opening • Life cycle	• Puncture resistance • Leak • Stability • Impact • Stacking • Vibration	Unknown	Unknown

CONCLUSION

Based on the testing performed, including puncture resistance, impact with leak, stability, impact, stacking, vibration, accessory strength, repeated opening, and life cycle testing, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices. Based on the intended use, technological characteristics, performance data, and non-clinical tests performed, the subject devices (Red2Green Reusable Sharps Containers) are substantially equivalent to, and are as safe and as effective as, the legally marketed predicate devices.