August 11, 2021

International Marketing Specialists Inc.
% Charles Mack
Principal Engineer
IRC
2950 E Lindrick Drive
Chandler, Arizona 85249

Re: K203305
Trade/Device Name: Tiger Reusable Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK

Dear Charles Mack:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 8/6/21. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Clarence Murray, OHT4: Office of Surgical and Infection Control Devices, 301-796-0270, Clarence.Murray@fda.hhs.gov.

Sincerely,

Clarence W. Murray III -S

Clarence W. Murray, III, Ph.D.
Assistant 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

August 6, 2021

International Marketing Specialists, Inc
% Charles Mack
Correspondent
International Marketing Specialists, Inc.
Contact Address

Re: K203305
Trade/Device Name: Tiger Reusable Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: July 21, 2021
Received: July 26, 2021

Dear Charles Mack:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray III -S

Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203305

Device Name
Tiger Reusable Sharps Container

Indications for Use *(Describe)*
Tiger 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K203305

510(k) Summary (21 CFR §807.92)

Date of Preparation: August 4, 2021

I. Submitter Information:

Submitter Name: International Marketing Specialists, Inc.

Address: 1278 Highway 461, Somerset, Kentucky 42503

Contact Person: Mr. Rod Calderon, General Manager

US Agent and Correspondent

Mr. Charles Mack

Principal Engineer

IRC

2950 E Lindrick Drive, Chandler, Arizona 85249 USA

Tel: 931-625-4938

Email: charliemack@irc-us.com

II. Device

Trade Name: Tiger Reusable Sharps Container

Common Name: container, sharps

Regulation Number: 21 CFR§880.5570

Regulation Name: Hypodermic single lumen needle

Regulatory Class: II

Product Code: MMK

III. Predicate Device Information

Manufacturer	Predicate Device	510(k) Number
Triumvirate Environmental, Inc.	Red2Green Reusable Sharps Container	K153363

IV. Device Description:

Tiger Reusable Sharps Containers are of injection-molded polypropylene plastic, designed for reusable 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.

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 product identification label's level line.

Parts & Accessories	Material	Material Specification	Patient Contact (Direct /Indirect)?
Base	Polypropylene	INEOS PP N02G-00	No
Lid	Polyethylene, High Density	ExxonMobil™ HDPE HD 6719 Series	No
Color power	Hififast Scarlet HF4Y	PPR007BTS	No

V. Indications for Use

Tiger 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.

VI. Intended Use

The containers are 100 times reusable, non-sterile, 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 qualified personnel in healthcare facilities and other facilities in which medical sharps may be used. All device models are not for use in areas with unsupervised patient access.

All device models only are used with appropriate mounting accessories.

Model	Weight (empty)	Capacity (total)	Capacity (full line)	Dimensions of finished goods (mm) (L x W x H)	Colors	Acceptable sites of use
2 Gallon Cap	875 g	7.8 Quarts	6 Quarts	331.98 x 154.48 x 324.2	Red base and white lid	The target population is qualified personnel in health care facilities and other facilities in which medical sharps may be used. All the containers are intended to be used in areas where there is no unsupervised patient access.
2 Gallon mailbox	1042 g	7.8 Quarts	6 Quarts	332.09 x 154.78 x 398.37		
3 Gallon Cap	1187 g	2.9 gallons	2.45 gallons	331.98 x 154.48 x 475.2		
3 Gallon mailbox	1354 g	2.9 gallons	2.45 gallons	332.09 x 154.78 x 549.37		
8 Gallon	1400 g	7.8 Gal	6.5 Gal	306.36 x 328.41 x 479.1		

Model	Lid configuration	Dimensions of lid opening (aperture)	Permanent Locking mechanism	Temporary Locking mechanism lid to container	Requirements for mounting
2-gallon cap	Cap/drop	63.54 mm	Hand pressure tight	Catamount Standard Cable ties on each side.	a. Locking wall bracket b. Wall enclosure
2-gallon mailbox	Mailbox	21.63 mm	Counterbalance door/ hinge closure	Catamount Standard Cable ties on each side	a. Locking wall bracket b. Wall enclosure
3-gallon cap	Cap/drop	63.54 mm	Hand pressure tight	Catamount Standard Cable ties on each side	a. Locking wall bracket b. Wall enclosure
3-gallon mailbox	Mailbox	21.63 mm	Counterbalance door/ hinge closure	Catamount Standard Cable ties on each side	a. Locking wall bracket b. Wall enclosure
8 gallon	Cap/drop	63.54 mm	Hand pressure tight	Catamount Standard Cable ties on each side	Stainless steel or plastic stabilizer/holder

VII. Comparison of Technological Characteristics with the Predicate Device

Element of comparison	Subject Device	Predicate Device	Comparison
Company	International Marketing Specialists, Inc.	Triumvirate Environmental, Inc.	N/A
FDA510(K) Number	Pending	K153363	N/A
Device Name	Tiger Reusable Sharps Container	Red2Green Reusable Sharps Container	N/A
Model Types	2 Gallon cap 2 Gallon mailbox 3 Gallon cap 3 Gallon mailbox 8 Gallon	2 Gallon 3 Gallon 8 Gallon	Identical
Indications for Use	Tiger 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.	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.	Identical
Product Code	MMK	MMK	Identical
Regulation Number	21CFR880.5570	21CFR880.5570	Identical
Class	2	2	Identical
Prescribed	OTC	OTC	Identical
Material	Polyethylene	Polyethylene	Identical
Dimensions (L x W x H)	2 Gallon cap: 331.98 x 154.48 x 324.2 (mm) 2 Gallon mailbox: 332.09 x 154.78 x 398.37 (mm) 3 Gallon cap: 331.98 x 154.48 x 475.2 (mm) 3 Gallon mailbox: 332.09 x 154.78 x 549.37 (mm) 8 Gallon: 306.36 x 328.41 x 479.1 (mm)	2 gallon: 6.3 x 12.8 x 10.4 (inches) 3 gallon: 6.3 x 12.8 x 15.3 (inches) 8 gallon: 13 x 13 x 17.4 (inches)	The same capacity but dimension difference doesn't raise new safety and effectiveness issues and confirm the design requirement.
Intended Location of Use	Health care facilities	Health care facilities	Identical

Element of comparison	Subject Device	Predicate Device	Comparison
Color	Red	Red or yellow	Identical
Needle Removal Mechanism	No	No	Identical
Sharps access and closure	Gravity-activated	Gravity-activated	Identical
Container Closure	Vertical and horizontal drop, lab lid, transportation lid	Vertical and horizontal drop, lab lid, transportation lid	Identical
Accessories	Wall enclosure, wall brackets	Stabilizing tray, wall enclosure, wall bracket, rolling dolly, foot pedal dolly	Identical
Reusable or Non-reusable Container	Reusable	Reusable	Identical
Non-sterile	Yes	Yes	Identical
Performance testing	Container stability Strength of handles Aperture and closure Resistance to penetration Resistance to damage or leakage after dropping Resistance to spillage by toppling Fill line Accessory strength	Puncture resistance Impact w/ leak Stability Accessory strength	The subject device confirms the FDA recently recognized performance standards for reusable sharps containers, including ISO 23907 First edition 2012-09-01, ISO 23907-2 First edition 2019-11, ASTM F2132-01 (reapproved 2008). The test conducted by predict device at past now already included in the FDA recognized performance standards.

Element of comparison	Subject Device	Predicate Device	Comparison
Lifespan Simulation Testing	Lifespan tumbling simulation Lifespan transport simulations Lifespan processing simulation	Repeated opening Life cycle	The subject device confirms to the FDA recently recognized performance standards for reusable sharps containers, including ISO 23907 First edition 2012-09-01, ISO 23907-2 First edition 2019-11, ASTM F2132-01 (reapproved 2008); The test conducted by predict device at past now already included in the FDA recognized performance standards.
Transportation Test	Impact Stacking Vibration	Impact Stacking Vibration	Identical: Conforms to 49 CFR 178.603 Conforms to 49 CFR 178.606 Conforms to 49 CFR 178.608
Biological Testing	ISO 0993-5, ISO 10993-10, ISO/DIS 15883-5, In vitro cytotoxicity, skin sensitization, cleaning efficacy.	The predicate is N/A for this testing.	N/A
Disinfection	Microbiological Challenge Test, Decontamination Assurance Level of 10-4	The predicate is N/A for this testing.	N/A

IX. Summary of Non-Clinical Testing

Performance Data

Performance testing was provided to demonstrate that the Tiger Reusable Sharps Container met the acceptance criteria or specifications found in the standards and guidance provided below.

Performance Testing

Test	Standard	Acceptance Criteria	Results
Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps	ASTM F 2132 -01 (Reapproved 2008)e1	The force needed to penetrate test specimens shall be a minimum of 20 N or greater.	Pass
DOT Drop Test	49 CFR 178.603	There is no damage to the outer packaging likely to adversely affect safety during transport, there is no leakage of the filling substance from the inner packaging。	Pass
DOT Stacking Test	49 CFR 178.606	No test sample may show any deterioration or distortion , which could adversely affect safety or container strength during transport causing instability in stacks of packages.	Pass

Test	Standard	Acceptance Criteria	Results
DOT Vibration standard	49 CFR 178.608	A packaging passes the vibration test if there is no rupture or leakage from any of the packages. No test sample should show any deterioration which could adversely affect transportation safety or any distortion liable to reduce packaging strength.	Pass
Container stability	ISO 23907 ISO 23907-2	The container shall not topple over when tested	Pass
Aperture and closure	ISO 23907 ISO 23907-2	It shall be possible to place sharps into the sharps container without using a second hand to manipulate the aperture. The aperture of containers intended to be placed in public access areas should be designed to restrict hand entry and removal of contents from the container. The aperture should be designed to prevent the risk of overfilling.	Pass
Resistance to penetration	ISO 23907 ISO 23907-2 ASTM F2132-01	The force needed to penetrate test specimens shall be a minimum of 20 N or greater.	Pass

Test	Standard	Acceptance Criteria	Results
Resistance to damage or leakage after dropping	ISO 23907 ISO 23907-2	There shall be no evidence of leakage and no breach of the sharps containment area. Minimum five minutes after every topple: - There shall be no evidence that the performance or function of the container has been compromised. - The container's temporary closure shall remain intact.	Pass
Resistance to spillage by toppling	ISO 23907 ISO 23907-2	There shall be no evidence of leakage and no breach of the sharps containment area. Minimum five minutes after every topple: - There shall be no evidence that the performance or function of the container has been compromised. - The container's temporary closure shall remain intact.	Pass

Test	Standard	Acceptance Criteria	Results
Accessory strength test	ISO 23907 ISO 23907-2	The strength of Wall Enclosures and Metal Wall brackets shall be tested by filling their associated sharps container with water. The filled container shall be placed into one of each of the respective wall-mounted accessories. After 48 hours, the containers shall be removed, and the accessories shall be inspected for any loss of integrity. There shall be no evidence of sagging, breakage, liquid leakage, or changes in performance for the locking mechanisms	Pass
Fill line	ISO 23907 ISO 23907-2	The fill line indicator shall be determined by the design of the container, considering the risk of sharps extending above the fill line. It shall be at a level no greater than 85 % of the total capacity of the container.	Pass

Test	Standard	Acceptance Criteria	Results
Lifespan simulation testing	ISO 23907 First edition 2012-09-01 ASTM F2132-01 (reapproved 2008) ISO 23907-2 First edition 2019-11	To verify the performance of the devices conforms to the applicable performance standards requirement after Lifespan Simulation Testing.	Pass
Cytotoxicity Tests	ISO10993-5	8.6 Evaluation Criteria	Based on the conditions of the test, the device was found to be non-cytotoxic
Skin Sensitization Test	ISO10993-10	9.4 Evaluation of results	Based on the conditions of the test, the device was found to be non-sensitizing
Skin Irritation Test	ISO10993-10	9.4 Evaluation of results	Based on the conditions of the test, the device was found to be non-irritating
Chemical Residues Test	ISO/DIS 15883-5	5.3 Quantitative Study of Extracts	Pass
Cleaning Validation	FDA Guidance AAMI TIR 30 ISO/DIS 15883-5	1 Evaluation pass/fail criteria for the residual protein and hemoglobin (blood) by Spectrophotometric method (Method 1) 2 Evaluation pass/fail criteria for residual TOC by total organic carbon analyzer (Method 2)	Pass

Test	Standard	Acceptance Criteria	Results
Disinfection Validation	FDA Guidance AAMI TIR 30 ISO/DIS 15883-5	The disinfection process should be deemed effective if all three of the following are met: The concentration of the challenge suspension meets 1.1.2 c) requirements. The positive control 1.2.2 e) shows microbial growth of each challenge organism. After processing, no challenge organism was recovered at any site.	Pass

The test results demonstrate the subject devices comply with the applicable requirements.

Clinical Test:
Not applicable.

X. Conclusions:

The non-clinical data demonstrate that the Tiger Reusable Sharps Container is as safe, as effective, and performs as well as or better than the predicate device, Red2Green Reusable Sharps Container (K153363) manufactured by Triumvirate Environmental, Inc.