May 31, 2019

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

Re: K190240
Trade/Device Name: Tiger Sharps Containers
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: April 21, 2019
Received: April 29, 2019

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,

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)*

K190240

Device Name

Tiger Sharps Containers

Indications for Use *(Describe)*

Tiger Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.

The Containers are single-use, disposable, non-sterile containers 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 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 be used with appropriate mounting accessories.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

| Model | Weight (empty) | Capacity (total) | Capacity (full line) | Dimensions of finished goods (in) (L x W x H) | Colors | Acceptable sites of use |
|---|---|---|---|---|---|---|
| 1 Quart | 109 grams | 28 Oz | 23.5 Oz | 3.91x3.91x6.37 | Red base and transparent lid | The target population is for 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. |
| 5 Quart | 450 grams | 140 Oz | 119 Oz | 10.60 x4.70x10.64 | | |
| 2 Gallon | 453 grams | 7.8 Quarts | 6 Quarts | 10.84x6.86x10.36 | | |
| 2 Gallon B | 453 grams | 7.8 Quarts | 6 Quarts | 10.22x7.02x13.30 | | |
| 15 liter | 625 grams | 15 liter | 12 liter | 9.50x14.77x12.03 | | |
| 3 Gallon | 559 grams | 2.9 Gal | 2.45 Gal | 14.86x7.25x14.00 | | |
| 8 Gallon | 1172 grams | 7.8 Gal | 6.5 Gal | 10.92x15.61x17.27 | | |

| Model | Lid configuration | Dimensions of Sharps disposal aperture (inches) | Locking mechanism | Needle unwinder | Requirements for mounting |
|---|---|---|---|---|---|
| 1 Quart | Dual opening Hinge | Opening 1: 1.70 x 1.18; Opening 2: 0.7 diameter; Opening 3: 0.83 x 0.31 | Hinged closure | located in the lid and above the containment area. The unwinder has a round entry port for the needle to pass through, allowing it to be fully enclosed within the container. | a. Non-Locking Wire Wall Bracket (Covidien)<br>b. Stabilizer/holder with Double face adhesive tape mounting<br>c. Free standing |
| 5 Quart | Counter Balance | 8.67 x 2.36 x 2.27 | Hinged closure | | a. Locking wall bracket (Covidien)<br>b. Wall enclosure<br>c. Free standing |
| 2 Gallon | Sliding | 2.40 x 5.04 | Sliding | | a. Locking wall bracket (Covidien)<br>b. Plastic wall bracket<br>c. Stainless steel or plastic stabilizer/holder<br>d. Free standing |
| 2 Gallon B | Star Hinge | 2.83 Diameter | Sliding | | a. Locking wall bracket (Covidien)<br>b. Plastic wall bracket<br>c. Stainless steel or plastic stabilizer/holder<br>d. Free standing |
| 15 liter | Sliding | 9.98 x 3.43 | Sliding | | a. Stainless steel or plastic stabilizer/holder<br>b. Free standing |
| 3 Gallon | Counter Balance | 9.37 x 3.34 | Counterbalanced door | | a. Locking wire bracket (Bemis)<br>b. Plastic wall bracket<br>c. Plastic stabilizer/holder<br>d. Free standing |
| 8 Gallon | Rotary/Hinge | 3.94 x 1.70 | Rotary door and hinge closure | | a. Stainless steel or plastic stabilizer/holder<br>b. Free standing |

**510(k) Summary**
Date of Preparation: April 21, 2019

## I. Submitter Information:


| | |
|---|---|
| Submitter Name: | International Marketing Specialists Inc. |
| Address: | 1278 Highway 461, Somerset, Kentucky 42503 |
| Contact Person: | Mr. Rod Calderon, 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 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 | Submitted Device |
|---|---|---|---|
| Medline Sharps Containers | Medline Sharps Containers | K143693 | Tiger Sharps Containers |

## IV. Device Description:

Tiger Sharps Containers constructed of injection molded polypropylene plastic. They are designed for a single-use (disposable) 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.

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 level line on the product identification label.

| **Parts & Accessories** | **Material** | **Material Specification** | **Patient Contact (Direct /Indirect)?** |
|---|---|---|---|
| Lid | Polypropylene | Formolene® Polypropylene Homopolymer | No |
| Base | Polypropylene | Formolene® Polypropylene Homopolymer | No |
| Color power | Hififast Scarlet HF4Y | PPR007BTS | No |

## V. Intended Use / Indications for Use

Tiger Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal.

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All device models only are used with appropriate mounting accessories.

| Model | Weight (empty) | Capacity (total) | Capacity (full line) | Dimensions of finished goods (in) (L x W x H) | Colors | Acceptable sites of use |
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| 5 Quart | Counter Balance | 8.67 x 2.36 x 2.27 | Hinged closure | | a. Locking wall bracket (Covidien)<br>b. Wall enclosure<br>c. Freestanding |
| 2 Gallon | Sliding | 2.40 x 5.04 | Sliding | | a. Locking wall bracket (Covidien)<br>b. Plastic wall bracket<br>c. Stainless steel or plastic stabilizer/holder<br>d. Freestanding |

| | | | | | |
|---|---|---|---|---|---|
| 2 Gallon B | Star Hinge | 2.83 Diameter | Sliding | | a. Locking wall bracket (Covidien)<br>b. Plastic wall bracket<br>c. Stainless steel or plastic stabilizer/holder<br>d. Freestanding |
| 15 liter | Sliding | 9.98 x 3.43 | Sliding | | a. Stainless steel or plastic stabilizer/holder<br>b. Freestanding |
| 3 Gallon | Counter Balance | 9.37 x 3.34 | Counterbalanced door | | a. Locking wire bracket (Bemis)<br>b. Plastic wall bracket<br>c. Plastic stabilizer/holder<br>d. Free standing |
| 8 Gallon | Rotary/Hinge | 3.94 x 1.70 | Rotary door and hinge closure | | a. Stainless steel or plastic stabilizer/holder<br>b. Freestanding |

**Comparison of Technological Characteristics with the Predicate Device**

| Element of comparison | Subject Device | Predicate Device |
|---|---|---|
| Company | International Marketing Specialists Inc. | Medline Industries, Inc. |
| FDA510(K) Number | K190240 | K143693 |
| Device Name | Tiger Sharps Containers | Medline Sharps Containers |
| Intended Use | Tiger Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal. | Medline Sharps Containers are intended to provide a receptacle for used, contaminated medical sharps and act as an enclosure during transport to ultimate disposal. |
| Product Code | MMK | MMK |
| Regulation Number | 21CFR880.5570 | 21CFR880.5570 |
| Class | II | II |
| Capacities | 1 Quart / 5 Quart / 2 Gallon / 2 Gallon B / 15 Liter<br>3 Gallon/ 8 Gallon | 1G / 2G / 8G / 10G / 12G / 18G |
| Prescribed | OTC | OTC |
| Weight Range (grams) | 109 - 1172 | 303 - 2388 |
| No. of Piece | 2-3 | 2-3 |
| Material | Polypropylene | Polypropylene |
| Color | Base: Red<br>Lid: Transparent | Red |
| Clarity | Opaque/translucent | Opaque/translucent |
| Non-sterile | Yes | Yes |
| Method of Manufacture | Injection Molded | Injection Molded |
| Performance testing *(puncture, impact, drop, stability, integrity etc.)* | Pass | Pass |
| Standards | ISO 23907, ASTM F 2132 | ISO 23907, ASTM F 2132 |
| Disposable or Re-usable? | Disposable | Disposable |

## VI. Non Clinical Performance Testing:

Performance testing was provided in support of the substantial equivalence determination and to validate and verify that the Tiger Sharps Container met all of the requirements of related international standards, including biocompatibility, sterility, and product specifications. Results of these tests demonstrate compliance with the requirements of the consensus standards noted below.

**Performance Testing**

The following performance tests were conducted for the subject device:
Puncture: per ASTM< F2132-01(2008)e1 = Pass
Resistance to Damage/Leaking after Drop: per ISO 23907-2012 = Pass
Handle Strength: per ISO 23907-2012 = Pass
Container Stability: per ISO 23907-2012 = Pass
Stacking: Per 49 CFR 178.606 = Pass
Vibration: Per 49 CFR 178.608 = Pass
Drop test: Per 49 CFR 178.603 = Pass

**Sterility Information**

The Tiger Sharps container is non-sterile; therefore no sterility testing was performed.

**Clinical Testing:**

Not Applicable.

## VIII. Conclusions:

The non-clinical data demonstrate that the Tiger Sharps Container is as safe, as effective, and performs as well as the predicate device, Medline Sharps Containers , cleared under K143693.