June 16, 2023

Ningbo Maxcon Medical Technology Co., Ltd.
% Henry Zhang
President
Shenglin (Hangzhou) Consultants Inc.
Room 2506, Unit 1#, Building 5#, Ronghui Business Center,
Economic Development Zone
Hangzhou, Zhejiang 310018
China

Re: K222906
Trade/Device Name: Maxcon Reusable Sharps Container, 17 Gallon Sharps Container MA1421
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: May 10, 2023
Received: May 17, 2023

Dear Henry Zhang:

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, PhD
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

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)*
K222906

Device Name
Maxcon Reusable Sharps Container17 Gallon Reusable Sharps Container MA1421

Indications for Use *(Describe)*
Maxcon Reusable Sharps Container is intended to be used for the collection and transportation of used medical sharps. The container is intended to be used in hospitals and clinics, operating rooms, and laboratories by technicians, doctors, dentists, and veterinarians. The device is only intended for use in areas with 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.

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宁波迈克斯康医疗科技有限公司
Ningbo Maxcon Medical Technology Co., Ltd

K222906: 510(k) Summary

1. **Date Prepared:** June 10, 2023

2. **Submitted by:**

Mr. Puhai Ma

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No.228,Dongxin Road,Dongqiao Town,.Ningbo,Zhejiang province,China

Establishment Registration Number: 3013584693

3. **Primary Contact:**

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4. **Name of the Device**

Common Name：Sharps Container

Trade Name:Maxcon Reusable Sharps Container

Model: 17 Gallon Reusable Sharps Container MA1421

5. **Classification Information:**

Product Code: MMK

Device Class: Class II

CFR Reference: 21 CFR 880.5570

Classification: hypodermic single lumen needles

Classification Panel:General Hospital

6. Predicate Device Information:

- **Primary Predicate Device:**

Trade name:Sharps Tank Reusable Sharps Container

The device (K111085), manufactured by Rehrig Pacific Company, located in 614 Hunters Lane, Brentwood, Tennessee 37027, USA.

Common name： Sharps Container,

Product code: MMK

Classification:Hypodermic single lumen needles

CFR Reference: 21CFR 880.5570-Class II

Classification Panel: General Hospital

- **Second Predicate Device:**

Trade name:Med-Tainer Single Deposit Container (SDC)

The device (K153274) manufactured by Snyder Industries, Inc., located in 6940 O Street, Suite 100,Lincoln, NE 68510, USA.

Common name： Sharps Container,

Product code: MMK

Classification:Hypodermic single lumen needles

CFR Reference: 21CFR 880.5570-Class II

Classification Panel: General Hospital

7. Intended Use / Indication for Use:

Maxcon Reusable Sharps Container is intended to be used for the collection and transportation of used medical sharps. The container is intended to be used in hospitals and clinics, operating rooms, and laboratories by technicians, doctors, dentists, and veterinarians. The device is only intended for use in areas with no unsupervised patient access.

8. Device Description:

Maxcon Reusable Sharps Container is of injection molded high density polyethylene plastic, and designed for a multiple-use of 250 cycles by qualified personnel in health care facilities and other facilities in which medical sharps may be used. No part of the container is intended to come in contact with patients. The containers are designed to be non-sterile, puncture resistant, leak resistant on the sides and bottom, impact resistant, closable and stable. The recommended fill level is engraved onto the plastic and corresponds to the product identification label's level line. The container body is in the color of red, while the container lid is in the color of black. The products are supplied to waste management companies that are responsible for transporting, decanting, decontaminating, and destroying the containers. The black lid is used to slide across the container top. When in use, move the lid to show an opening with a size depending on the sharps waste to be dropped, and drop sharps waste into the container safely and effectively by gravitational force, allows easy disposal of sharps. After the sharps is deposited, slide the lid closed along the groove to recover the container body for temporary closure. When the content reaching to the fill line, use a 6" cable tie to lock together the lid and container body for final closure. The container is not for use in area with unsupervised patient access.

General Specifications of the Sharps Container

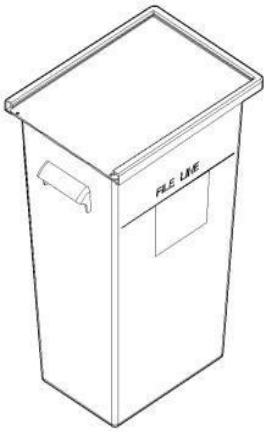
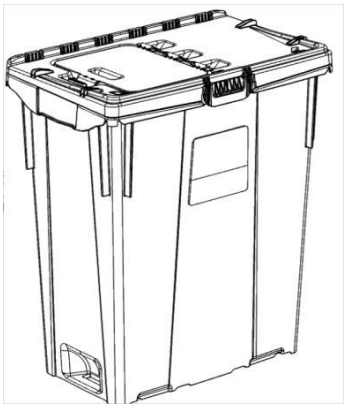
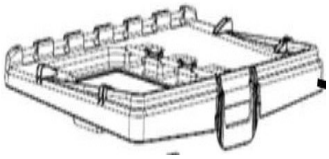
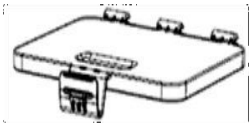
Model	Weight (empty)gram	Capacity (total)	Capacity (full line)	Dimensions of finished goods (mm) (L x W x H)	Colors	Acceptable sites of use
MA1421	3760	17 gallon	13.6 gallon	445.5*335*631.5	Red	The target population is for qualified personnel in health care facilities and other facilities in which medical sharps may be used. All the containers are intended to be used in areas where there is no unsupervised patient access.

General Description of the Lid

Model	Lid configuration	Dimensions of Sharps disposal aperture (mm)	Color	Temporary Locking mechanism lid to container	Permanent Locking mechanism
MA1421	One lid (lid number: MA1400Z(R)	416*280	Black	Slid the lid along the groove to cover the container body .	Lock together the lid and the container body by a cable tie

9. Technological Characteristics Comparison:

Characteristic	Submitted Subject Device	Primary Predicate Device	Second predicate device	Comparison/Comments
510(k)	K222906	K111085	K153274	--
Device Name	Maxcon Sharps reusable container	Sharps Tank Reusable Sharps Container	Med-Tainer Single Deposit Container	--
Product code	MMK	MMK	MMK	Same
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	21 CFR 880.5570	Same
Class	II	II	II	Same
Indication for use	Maxcon Reusable Sharps Container is intended to be used for the collection and transportation of used medical sharps. The container is intended to be used in hospitals and clinics, operating rooms, and laboratories by technicians, doctors, dentists, and veterinarians. The device is only intended for use in areas with no unsupervised patient access.	Rehrig Healthcare Systems reusable 17gallon sharps container is intended to be used for the collection and transportation of used medical sharps. The container is intended to be used in hospitals and clinics, operating rooms, and laboratories by technicians, doctors, dentists, and veterinarians. The device is only intended for use in areas with no unsupervised patient access.	Med-Tainer Single Deposit Containers are intended for the safe collection and transport of medical sharps. The reusable 10gallon and 17gallon containers are to be used in supervised areas of healthcare institutions such as hospitals, clinics, veterinary offices and laboratories. The Med-Tainer Single Deposit Container is available in Kelly green, Ascent blue, teal, red and yellow.	Same

Physical properties				
Model	MA1421	MW009	780310E74100	NA
Weight and Capacity	8.3pounds and 17gallons	9.4 pounds and 17 gallons	7pounds and 17 gallons	Similar, no new issues of safety or effectiveness
Product Picture			Unavailable	Similar, no new issues of safety or effectiveness
Lid Style Illustration		Main Lid  Sub Lid 	Unavailable	Different styles. Subject Device is flat plate slider style and Predicate device is hinged design. Both can be secured in place for transport and both met test requirements of the Standard, so no new issues of safety or efficacy.
Approximate Size	445.5mm Length 335mm Width 631.5mm Height	508mm Length 317.5mm Width 655.3mm Height 20.00"L x 12.50"W x 25.8"H	457.2mm Length 330.2mm Width 635mm Height 18 "L x 13 "W x 25"	Similar, no new issues of safety or effectiveness
Opening dimensions (length x width)	416mm x 280mm total (maximum) and variable slide-opening up to the maximum for sharps deposit with slide control	457.2mm x 271.8mm total and hinged-opening of 203.2mm x 152.4mm for sharps deposit	146.1mm x 247.7mm for sharps deposit	Similar, no new issues of safety or effectiveness

Target population	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	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	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	Same
Color	Red, with embossed and inked fill line; contrasting label includes Biohazard symbol	Red with contrasting Biohazard Symbol	Red with embossed and inked fill line; contrasting label includes Biohazard symbol	Similar, No new issues of safety or effectiveness
Material of construction	High density polyethylene	High density polyethylene	Linear Low density polyethylene	Similar, No new issues of safety or effectiveness
Reprocessing solution	hot water (82°C) and 5.25% hypochlorite solution diluted to 1:10 part hot water (82°C)	hot water (82°C) and 5.25% hypochlorite solution diluted to 1:10 part hot water (82°C)	unavailable	Similar, No new issues of safety or effectiveness
Whether reprocessing steps are required to be automatic or not	Yes	Yes	Yes	Same
Requirement for Reprocessing Site				
Working environment	Operating Temperatures :20° - 30°C Storage Temperature :20° - 30°C Transportation Temperature:0° - 38°C	Operating Temperatures :20° - 30°C Storage Temperature :20° - 30°C Transportation Temperature:0° - 38°C	Unavailable	Same as primary predicate device
Training	Please read user manual carefully, no special training is required	Please read user manual carefully, no special training is required	Unavailable	Same as primary predicate device
Expected controls and Qualification methods	The recommended guidelines for decanting and decontamination are provided in the user manual and it is recommended that the decanting/cleaning facility develop cycles and processes through a formal qualification process based on the specific automatic machines to be used	The recommended guidelines for decanting and decontamination are provided in the user manual and it is recommended that the decanting/cleaning facility develop cycles and processes through a formal qualification process based on the specific automatic machines to be used	Unavailable	Same as primary predicate device

Method of Manufacture	Injection Molded	Injection Molded	Rotationally molded	Different No new issues of safety or effectiveness
Technological properties				
Sterile or non-sterile	Non-sterile	Non-sterile	Non-sterile	Same
Reusable or not	Reusable	Reusable	Reusable	Same
Reusable cycles	250 cycles	400 cycles	750 cycles	Different, defined in labeling so no new issues of safety or effectiveness
Performance testing (Non-Clinical Testing)				
Life Span Processing Simulation	Meets requirements of ISO23907-2:2019, Reusable sharps containers, Sharps injury protection - Requirements and test methods - Sharps containers - Part 2: Reusable sharps containers. (Containers were processed 250 times to simulate their intended life cycle: filled with sharps, closed for transport, opened, decanted, rinsed and decontaminated.	Unavailable	Met requirements of CAN/CSA Z316.6-14 BA.8.3.1, Sharps injury protection – Requirements and test methods - Sharps containers. (Containers were processed 780 times to simulate their intended life cycle: filled with sharps, closed for transport, opened, decanted, rinsed and decontaminated.)	Met requirements of the relevant and current standards/regulations that cite comparable requirements. No new issues of safety or effectiveness
Life Span Transport Simulation	Meets requirements of ISO23907-2:2019, Reusable sharps containers, Sharps injury protection - Requirements and test methods - Sharps containers - Part 2: Reusable sharps containers.	Unavailable	Met requirements of CAN/CSA Z316.6-14 BA.8.3.1, Sharps injury protection – Requirements and test methods - Sharps containers.	Met requirements of the relevant and current standards/regulations that cite comparable requirements. No new issues of safety or effectiveness
Container Stability Test	Meets requirements of ISO23907-2:2019, Reusable sharps containers, Sharps injury protection - Requirements and test methods - Sharps containers - Part 2: Reusable sharps containers.	Unavailable	Met requirement of ISO23907:2012, Sharps injury protection Requirements and test methods – Sharps containers	Met requirements of the relevant and current standards/regulations that cite comparable requirements. No new issues of safety or effectiveness

Strength of Handles	Meets requirements of ISO23907-2:2019, Reusable sharps containers, Sharps injury protection - Requirements and test methods - Sharps containers - Part 2: Reusable sharps containers.	Unavailable	Met requirement of ISO23907:2012, Sharps injury protection Requirements and test methods – Sharps containers	Met requirements of the relevant and current standards/regulations that cite comparable requirements. No new issues of safety or effectiveness
Resistance to Damage and Leakage after Dropping	Meets requirements of ISO23907-2:2019, Reusable sharps containers, Sharps injury protection - Requirements and test methods - Sharps containers - Part 2: Reusable sharps containers.	Unavailable	Met requirement of ISO23907:2012, Sharps injury protection Requirements and test methods – Sharps containers	Met requirements of the relevant and current standards/regulations that cite comparable requirements. No new issues of safety or effectiveness
Resistance to penetration	Meets requirements of ISO23907-2:2019, Reusable sharps containers, Sharps injury protection - Requirements and test methods - Sharps containers - Part 2: Reusable sharps containers. (The criteria to pass is the penetration force shall be a minimum of 20N or greater)	Unavailable	Met requirements for Puncture Resistance per ASTM F2132-01 Standard Specification of Materials Used in Containers for Discarded Medical Needles and Other Sharps. (The criteria to pass the puncture resistance test are an average value not less than 3.4 lbf (15 N) with no value less than 2.8lbf or 12.5 N).	Met requirements of the relevant and current standards/regulations that cite comparable requirements. No new issues of safety or effectiveness
Stack Test	178.606, Specification for Packagings – Subpart M – Testing of Non-Bulk Packaging and Packages	Unavailable	Met requirements of 49 CFR 178.606 Specification for Packagings – Subpart M – Testing of Non-Bulk Packaging and Packages	Meet current requirements, No new issues of safety or effectiveness

Vibration Testing	Met requirements of 49 CFR 178.608 Specification for Packagings – Subpart M – Testing of Non-Bulk Packagings and Packages	Unavailable	Met requirements of 49 CFR 178.608 Specification for Packagings – Subpart M – Testing of Non-Bulk Packagings and Packages	Meet current requirements, No new issues of safety or effectiveness

Cleaning Validation	Meets requirements of ISO23907-2:2019, Reusable sharps containers, Sharps injury protection - Requirements and test methods - Sharps containers - Part 2: Reusable sharps containers.	Unavailable	Met requirements per FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling	Meet current requirements, No new issues of safety or effectiveness

10. Summary of Non-Clinical Tests:

Maxcon Reusable Sharps Containers have the same indications for use and technological characteristics as the predicate device(s). The results of non-clinical testing demonstrated that the subject device successfully met requirements, as follows:

Test Conducted	Standard	Acceptance Criteria	Results
Tumbling with sharps simulation	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	No rupture, leakage, or deterioration that could adversely affect its safe use or functionality.	Passed
Transport Simulations	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	No rupture, leakage, or deterioration that could adversely affect its safe use or functionality.	Passed
Process simulations, including opening, decanting, decontamination, and closing processes of 250 cycles	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	No rupture, leakage, or deterioration that could adversely affect its safe use or functionality.	Passed
Container Stability	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	Container shall not topple over	Passed
Strength of Handles	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	Handle/carrying feature shall not break or detach	Passed
Resistance to penetration	ISO 23907-2:2019 Sharps injury	Force needed to penetrate test	Passed

	protection - Requirements and test methods, Part 2: Reusable sharps containers	specimens shall be a minimum of 20 N or greater.	
Resistance to damage and leakage after dropping	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	No evidence of leakage and no breach of the sharps containment area.	Passed
Label Integrity Test	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	Labels are intact and legible after decontamination processing	Passed
Resistance to spillage by toppling	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	No evidence of breach of the sharps containment are	Passed
Microbiological validation	ISO 23907-2:2019 Sharps injury protection - Requirements and test methods, Part 2: Reusable sharps containers	No organisms are recovered from areas where a 104/ml challenge-suspension of representative pathogens in whole blood has been applied and dried.	Passed
Stacking Test	49CFR 178.606	No leakage, deterioration, buckling that might affect transportation safety or damage to contents	Passed
Vibration Test	49CFR 178.608	No rupture or leakage	Passed
Usable Capacity Test	----	The real using capacity should be ± 3% different from designed capacity.	Passed
Leak Proof on the	-----	The side and bottom	Passed

sides and bottom		should be of no water leakage after soaking with water for 24 hours.	

11. Sterility Information

The subject device container is non-sterile; therefore, no sterility testing was performed.

12. Discussion of Clinical Tests Performed:

There was no clinical testing required to support the review of this medical device.

13. Conclusions:

The Maxcon Reusable Sharps Container, as designed and manufactured, is as safe, as effective, and performs as well as or better than the legally marketed device identified in this submission.