January 3, 2019

Ningbo Maxcon Medical Technology Co., Ltd.
Yang Song
Sales Manager
No.30 Dongbei Road/No.228 Dong Xin Road, Dong Qiao Town
Ningbo, 315157 Cn

Re: K180984
Trade/Device Name: Maxcon Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: November 21, 2018
Received: December 7, 2018

Dear Yang Song:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -S

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: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180984

Device Name
Maxcon Sharps Container

Indications for Use *(Describe)*
Maxcon Sharps containers (2.2 QT Sharps Container, MA1122; 2G Sharps Container MA1321; 2 G Sharp Container MA1221; 8G Sharps Container MA1352) 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 the containers are intended to be used in areas where there is 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

510(k) Summary

The assigned 510(k) number is: K180984

1. Date Prepared: January 3, 2019

2. Submitter's Identification:

Ningbo Maxcon Medical Technology Co.,Ltd

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

Contact person: Mr.Song Yang, Sales manager of business department Telephone：

(+86)18656003277

E-mail：song.yang@maxcon.net.cn

Zip code：315157

3. Name of the Device:

Device Name:Sharps Container

Trade Name:Maxcon Sharps Container

Including models:
2.2 QT Sharps Container, MA1122; 2G Sharps Container MA1321 ; 2 G Sharp Container MA1221; 8G Sharps Container MA1352

4. Classification Information:

Product Code: MMK

Device Class: Class II

CFR Reference: 21 CFR 880.5570

Classification: accessory to hypodermic single lumen needles

Classification Panel:General Hospital

5. Predicate Device Information:

Trade name: Oak Ridge Products Sharps Container, manufactured by Oak Ridge Products L.L.C, located in 4612 Century Court, McHenry, Illinois, 60050 USA

Common name: Sharps Container

Product code: MMK

Classification: Accessory to hypodermic single lumen needles

CFR Reference: 21CFR 880.5570-Class II

Classification Panel: General Hospital

Legally Marketed Equivalent Device:

Company	Product description	Oak Ridge part number	510(K)#
Oak Ridge Products	2.2 Quart Rotary Lid Sharps-rotary door	0322-150R	K161180 (Primary predicate）
Oak Ridge Product	1 Gallon Sharps Container-sliding door	0319-1500	K161180 (Primary predicate）
Oak Ridge Product	2 Gallon Sharps-w/folding door	0320-150F	K161180 (Primary predicate）
Oak Ridge Product	7 Gallon Sharps Container -hinged door	0370-1500	K141759 (Reference device)

6. Intended use / Indication for Use:

Maxcon Sharps containers (2.2 QT Sharps Container, MA1122; 2G Sharps Container MA1321 ; 2 G Sharp Container MA1221; 8G Sharps Container MA1352） 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 the containers are intended to be used in areas where there is no unsupervised patient access.

7. Device Description:

Maxcon Sharps Containers are made of injection molded polypropylene plastic, and designed for a single-use by qualified personnel in health care facilities and other

facilities in which medical sharps may be used, the same as that of the comparable predicate devices.

Maxcon Sharps Containers are composed of 3 parts (base+lid+closure).No part of the container is intended to come in contact with patients and the sharps objects that will be placed within the containers.The lid and the closure come pre-assembled with the base not attached. Components are nested together to reduce room occupation in storage and shipping. The final on-site assembly is performed in health care facility by snapping the lid to the base.

Labels are on a red background with printed in black text and a black bio-hazard symbol. Labels are adhered to the containers at the time of the manufacture with the fill line warning matching the engraved fill line on the container.

There is no feature to bend, break, or shear needle ,includes blunting and melting of needle in the containers.

Product Model	Product description and closure type	Access opening size (mm)	Overall size L× W× H(mm)	Weight (grams) empty	Total capacity	Capacity at full line	Mounting
MA1122	2.2 quart red sharps container-rotary door	86x38	160x120x 181	175	2.1 L	1.6 L	Free standing or double face adhesive tape
MA1221	2 gallon red sharps container-folding door	203x63	316x152x 230	421	7.5 L	6 L	Free standing or bracket
MA1321	2 gallon red sharps container-sliding door	139x61	275x180x 254	365	7.5 L	6 L	Free standing or bracket
MA1352	8 gallon red sharps container-hinged door	226x126	390x276x 435	1220	27.3L	21 L	Free-standing

The maximum allowable gross mass of the container is defined as follows:

Model	Maximum allowable gross mass in the container
MA1122	0.5kg
MA1321	2kg
MA1221	2kg
MA1352	8kg

Needle unwinder Feature:

The unwinder feature on the 2.2 quart container(model: MA1122, rotary door), 2 gallon container (model: MA1221, folding door) and 8 gallon container (model:MA1352, hinged door) is 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. 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 container without the need to be touch or handled.

8. Comparing to Predicate Device:

Characteristics	Subject device manufactured by Ningbo Maxcon Medical Technology Co.,Ltd	Predicate device Oak Ridge Products (K161180) (Predicate device)	Predicate device Oak Ridge Products (K141759) (Reference device)	S.E Comparison
Product code/class/regulation number	MMK/class II/ 21 CFR 880.5570	MMK/class II/ 21 CFR 880.5570	MMK/class II/ 21 CFR 880.5570	Same
Indications for use/intended use	Maxcon Sharps 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 the containers are intended to be used in areas where there is no unsupervised patient access.	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 professional.All the containers are intended to be used in areas where there is no unsupervised patient access.	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 professional.	Same
Device design	All is comprised of 3 components, a container base+a lid+a closure. Its closure is designed of 4 types: Rotary door ,Folding door, sliding door and hinged door. The lid and the closure come pre-assembled with the base not attached. Components are nested together to reduce storage and shipping requirements. The health care facility performs the final assembly on-site by snapping the lid to the base.			Same
Where it is used	Health care facility and other facility in which medical sharps may be used	Health care facility	Health care facility	Same
Materials used	Injection molded of Poly-propylene	Injection molded of Poly-propylene	Injection molded of Poly-propylene	Same
Size	2.2 Quart / 2 gallon / 2 gallon / 8 gallon	2.2 Quart / 1 Gallon / 2 Gallon	7 Gallon	Different
Dimensions (inches)	6.25×4.6×6.7 / 12.4x6x9 / 10.8x7.1x10 / 15.35x10.9x17.1	6.25×4.6×6.7 / 10.3×7.0×5.5 / 10.3×7.0×10.1	15.5×12×13.75	Different
Weight (grams)	175 / 421 / 365 / 1220	172 / 280 / 397	1228	Different
Access opening size(inches)	3.4×1.5 / 8×2.5 / 5.5×2.4 / 8.9x5 (Major), 3.4×1.5 (minor)	3.4×1.5 / 5.6×2.3 / 8.2×2.1	13.75×4.75 (Major), 8.75×1.75 (minor)	Different
Non-clinical testing	Successfully passed through tests of impact resistance, puncture resistance and leak resistance	Successfully passed through tests of impact resistance, puncture resistance and leak resistance	Successfully passed through tests of impact resistance, puncture resistance and leak resistance	Same
No features to bend, break, or shear needle	No feature present	No feature present	No feature present	Same

Clarity	Each container has one translucent component, allowing visibility to check whether the wasted sharp reach to fill line or not	Each container has one translucent component, allowing visibility to check whether the wasted sharp reach to fill line or not	Each container has one translucent component, allowing visibility to check whether the wasted sharp reach to fill line or not	Same
Capable of maintaining a stable and upright position	Yes	Yes	Yes	Same
Performance, effectiveness and safety	All container has been successfully passed through test items as follows: □ Puncture Resistance as per FDA Recognized Consensus Standards, 6-215, ASTM F2132 -01 Standard Specification for Puncture Resistance of Material Used in Containers for Discarded Medical Needles and Other Sharps (Reapproved 2008)e1, □ Container stability, as well as bracket stability as per FDA Recognized Consensus Standards, 6-293, ISO 23907 First edition 2012-09-01Sharps injury protection - Requirements and test methods - Sharps containers. □ Handle strength as per FDA Recognized Consensus Standards, 6-293 , ISO 23907 First edition 2012-09-01Sharps injury protection - Requirements and test methods - Sharps containers. □ Resistance to damage and leakage after dropping as per FDA Recognized Consensus Standards, 6-293, ISO 23907 First edition 2012-09-01Sharps injury protection - Requirements and test methods - Sharps containers. □ Occupational Safety and Health Administration - Occupational Exposure to Bloodborne Pathogens; final rule (29 CFR 1910.1030; Federal Register 1991 December 6; 56, No. 235:64175-82.			Same
End-color change	No color change	No color change	No color change	Same
Claimed sterilization cycles	Non sterile	Non sterile	Non sterile	Same
Operation way	Drop the wasted sharps into container by one hand	Drop the wasted sharps into container by one hand	Drop the wasted sharps into container by one hand	Same
Single use or not	Single used and disposable ones	Single used and disposable ones	Single used and disposable ones	Same
Labeling	Biohazard labels visible on device	Biohazard labels visible on device	Biohazard labels visible on device	Same

9. Performance Data

Maxcon Sharps Containers have similar indications for use and technological characteristics as the predicate device, based on the subject containers can be successfully passed through the tests as follows:

□ Puncture Resistance (based on ASTM F 2132-01 (2008)) – Passed

□ Container Stability (based on ISO 23907:2012)- Passed

□ Drop/impact Test (based on ISO 23907:2012)-Passed

□ Handle Strength (based on ISO 23907:2012)- Passed

□ Stacking Test (based on 49CFR 178.606)- Passed

□ Vibration Test (based on 49CFR 178.606)-Passed

□ Sharps access and closure for repeated openings and closings-Passed

□ Label Integrity Test (based on ISO23907:2012)-Passed

□ Usable Capacity Test-Passed

□ Minimum Sharps Container wall Thickness Evaluation-Passed

□ Shelf-life study (including real-time aging and accelerated-time aging to support its shelf life of 3 years)-Passed

□ Simulated life cycle test-Passed

□ Leak Proof on the sides and bottom-Passed

Although the subject device and predicate devices differ in containers size, dimensions, and containers capacities etc, the difference in technological characteristics do not impair the subject devices from their intended functions of disposal and storage of sharp waste, and did not compromise the SE (Substantially equivalent) to the predicated device.

10. Discussion of Clinical Tests Performed:

There was no clinical testing required to support the medical device

11. Conclusions:

We have demonstrated in this 510(k) submission that based on the nonclinical tests performed the subject devices, Maxcon Sharps containers (2.2 QT Sharps Container, MA1122; 2G Sharps Container MA1321 ; 2 G Sharp Container MA1221; 8G Sharps Container MA1352), are as safe, as effective and performs at least as safely and effectively as the legally marketed predicate devices (Oak

Ridge Products Sharps, K141759 (Reference device) and K161180(Primary predicate device), Class II (21 CFR 880.5570), product code MMK