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: K180983
Trade/Device Name: Maxcon Two Gallon Chemotherapy Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: MMK
Dated: November 22, 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: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180983

Device Name
Maxcon Two Gallon Chemotherapy Container (Model, MC1321）

Indications for Use *(Describe)*
Maxcon Two Gallon Chemotherapy Container (Model, MC1321） is intended for safe collection and containment of trace chemotherapy waste including needles, syringes, and empty vials.The container is non-sterile, to be single-used in areas with controlled access, such as nurse's stations, pharmacies and chemo treatment rooms, and the target population is for trained health-care professionals.

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:**K180983**

1. **Date Prepared:** December 29, 2018

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:**

Common Name:Sharps Disposal Container

Trade Name:Maxcon Two Gallon Chemotherapy Container (Model: MC1321)

Classification name: Hypodermic single lumen needle

4. **Classification Information:**

Product Code: MMK

Device Class: II

CFR Reference: 21 CFR880.5570

Classification Panel:General Hospital

5. **Predicate Device Information:**

The Maxcon Two Gallon Chemotherapy Containers (Model: MC1321) are equivalent to Bemis Two Gallon Chemotherapy Containers (K964858) manufactured by Bemis Manufacturing Company, located in 300 Mill Street, Sheboygan Falls, WI 53085, USA, which has the same intended use and is similar in design to the predicate devices.

6. **Intended use / Indication for Use:**

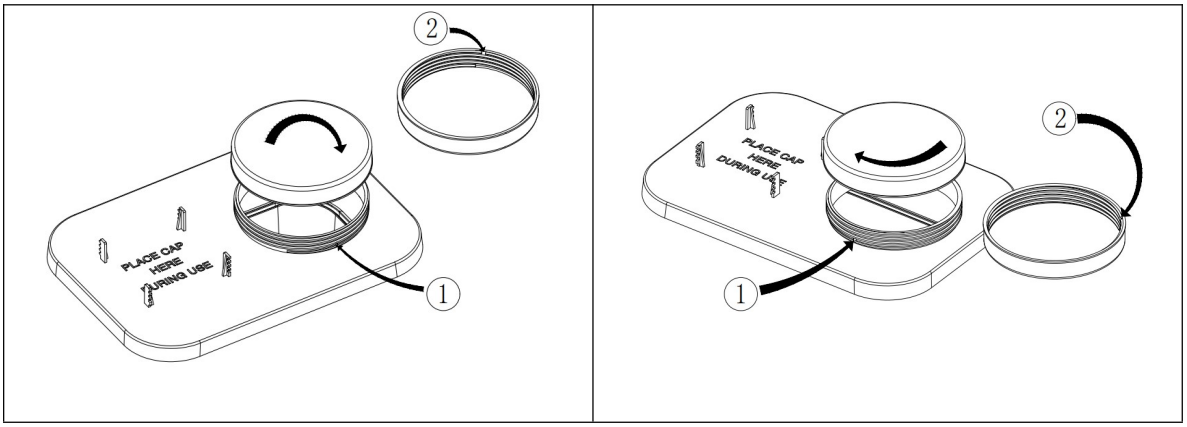
Maxcon Two Gallon Chemotherapy Container (Model, MC1321）is intended for safe collection and containment of trace chemotherapy waste including needles, syringes, and empty vials.The container is non-sterile, to be single-used in areas with controlled access, such as nurse's stations, pharmacies and chemo treatment rooms, and the target population is for trained health-care professionals.

7. Device Description:

Maxcon Two Gallon Chemotherapy Container (Model: MC1321) is of 2 gallon capability, weight about 470gram, size of 275.6mm (length) ×181.5mm (width)× 275mm (height), and the maximum allowable gross mass of the container defined by the company is 2 Kg.There is no feature to bend, break, or shear needle (includes blunting and melting of needle)in the containers.

The container is made of base+gasketed cap+screw-on cap. The plastic components are made of injection-moulded of Poly-propylene (PP). The pad and gasket are made of Ethylene Vinyl Acetate (EVA) foam.

The mechanism of temporarily locking and permanently locking



As Indicated in the above-mentioned pictures, there is a special structure embedded in the screw thread, which can lock the cap firmly and be resistant to manual opening.

1. A bulge located in the end of screw thread.
2. A gap located in the beginning of screw thread

When the cap is screwed to the end, the gap will engage the bulge, with a sound of click, and the cap will not be opened again.

Information of the container base

Size (mm)	Material	Weight	Color
275.6x181.5x275mm	PP	375 Gram	Translucent yellow

Wall Thickness of the container (mm)

Base thickness	Lid thickness	Cap thickness
1.6±0.1	1.6±0.1	1.6±0.1

The closure system is designed, comprising of 4 components:

Gasketed lid	Lid gasket pad	Screw-on cap	Cap gasket
Material: P.P Size: 181.5mmX261.4mm Weight：94 grams	Material::Ethylene Vinyl Acetate (EVA) foam Size: 175mmX255mm Weight：10 grams	Material: P.P Size: 108mmX17mm Weight：22 grams	Material: Ethylene Vinyl Acetate (EVA) foam Size: 103mmX1mm Weight：2 grams

8. Comparing to Predicate Device:

Characteristic	Proposed Device Maxcon Two Gallon Chemotherapy container (K180983) manufactured by Ningbo Maxcon Medical Technology Co.,Ltd with address in No.228,Dongxin Road,Dongqiao Town, Yinzhou.Ningbo,Zhejiang province,China	Predicate Device Bemis Two Gallon Chemotherapy Container (K964858) manufactured by Bemis Health Care with address in 300 Mill Street Sheboygan Falls, WI 53085, USA	S.E. Comparison
Product Code	MMK	MMK	Same
Regulation No.	21 CFR 880.5570	21 CFR 880.5570	Same
Class	II	II	Same
Indications For Use	Maxcon Two Gallon Chemotherapy Container (Model, MC1321）is intended for safe collection and containment of trace chemotherapy waste including needles, syringes, and empty vials.The container is non-sterile, to be single-used in areas with controlled access, such as nurse's stations, pharmacies and chemo treatment rooms, and the target population is for trained health-care professionals.	The Bemis Two Gallon Chemotherapy Container is a sharps disposal container.It is intended for the safe disposal of needles, syringes, and other chemotherapy waste in areas with controlled access which typically include nurse's stations, oncology, pharmacies, and chemotherapy treatment rooms.	Same
Size	2Gallon	2Gallon	Same
Dimensions	292mmx193mmx216 mm	215.9mmx292.1mmx193mm	Different
Weight range	470 gram	1LB 2OZ	Different
Material used of plastic components	Poly-propylene	Poly-propylene	Same
Material used of Pad and gasket	Ethylene Vinyl Acetate (EVA) foam	Ethylene Vinyl Acetate (EVA) foam	Same
Claimed sterilization cycles	Non-sterile	Non-sterile	same
End-color change	No color change	No color change	Same
Where it used	controlled access, such as nurse's	controlled access, such as nurse's	Same

	stations, pharmacies and chemo treatment rooms	stations, pharmacies and chemo treatment rooms	
Base Color	Yellow	Yellow	Same
Clarity	Translucent of the base,allowing visibility of fill level	Translucent of the base, allowing visibility of fill level	Same
Device design	Base+Gasketed lid +screw on plastic cap	Base+Gasketed lid +screw on plastic cap	Same
Single use or not	Single used and disposable ones	Single used and disposable ones	Same
Non-clinical testing	Successfully passed through tests of puncture resistance, leak resistance, stability,free standing and impact resistance	Successfully passed through tests of puncture resistance, leak resistance, stability,free standing and impact resistance	Same
Operation way	One-handed operation	One-handed operation	Same
Method of Manufacture	Injection Molded	Injection Molded	Same
Performance, effectiveness and safety	The containers successfully passed through the tests described in 1) 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, 2) FDA Recognized Consensus Standards, 6-293, ISO 23907 First edition 2012-09-01Sharps injury protection - Requirements and test methods - Sharps containers, 3) 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.	The predicated device was cleared in 1990s, with its test conducted as per: 1) ASTM proposed standard for puncture resistance/ECRI Puncture Resistance Criteria 2) ECRI Health Devices Leak Resistance Criteria 3) OSHA 4) ECRI free-standing capability criteria	Similar

9. Performance data

Maxcon Two Gallon Chemotherapy Container has similar indications for use and technological characteristics as the predicate device（K964858) manufactured by Bemis Health Care, based on the subject device, Maxcon Two Gallon Chemotherapy container, is found to successfully pass 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
- Test to demonstrate MAXCON TWO GALLON CHEMOTHERPAY CONTAINER suitable for chemotherapy drugs-Passed
- Chemical Resistance test (with H_2SO_4 and NaOH used to demonstrate its chemical resistance) -Passed
- Shelf-life study (including real-time aging and accelerated-time aging to support its shelf life of 3 years)-Passed

Therefore, although the subject device and predicate device differ in container dimensions and the weight, it is believed that the difference in technological characteristics do not impair the subject device from the intended functions of disposal and storage of trace chemotherapy waste including needles, syringes, and empty vials, 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 device, Maxcon Two Gallon Chemotherapy Container, is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device, Bemis Two Gallon Chemotherapy Container (K964858)