February 9, 2023

Shanghai Kindly Enterprise Development Group Co., Ltd.
Amy Li
Technology Director
No. 658 Gaochao Road
Shanghai, Shanghai 201803
China

Re: K223678
Trade/Device Name: Sterile Syringes for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: November 05, 2022
Received: December 8, 2022

Dear Amy Li:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2023.02.09 11:34:59 -05'00'

For CAPT Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K223678

Device Name
Sterile Syringes for Single Use

Indications for Use *(Describe)*
Sterile Syringes for Single Use are sterile, single-use, disposal, without needle and manually operated syringes intended to use with a 6% conical fitting device for injection of drug into the body. The syringes are intended for use immediately after filling and are not intended to contain the fluid/medication for extended periods of time.

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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K223678- 510(K) Summary

1. Date of preparation: February 9, 2023

2. Sponsor Identification

Shanghai Kindly Enterprise Development Group Co., Ltd.
658 Gaochao Road, Shanghai, 201803, China

Contact Person: Hualong Liu
Position: Technology Director
Tel: +86 02169118232
Email: henry_liu@kdlchina.net

3. Designated submission correspondent

Ms.Amy Lee(Primary Contact Person)
Mind-Link Consulting Co., Ltd.
Tel: +86 15721449974
Email: amy.li@mind-link.net

4. Identification of Proposed Device

Trade Name: Sterile Syringes for Single use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Regulation Number: 21 CFR 880.5860
Review Panel: General hospital

5. Indication for use

Sterile Syringes for Single Use are sterile, single-use, disposal, without needle and manually operated syringes intended to use with a 6% conical fitting device for injection of drug into the body. The syringes are intended for use immediately after filling and are not intended to contain the fluid/medication for extended periods of time.

6. Device description

KDL Sterile Syringes for Single Use are composed of barrel, plunger, and a moveable piston. The plunger does not contact any part of the fluid path, rather the plunger which attaches to the piston and the barrel are fluid path components. Materials of construction for the components have been shown to meet the applicable requirements of ISO 10993-1. Additionally, there is a small amount of lubricant for moving the plunger smoothly along the inside surface of the barrel. The connector is a universal luer threaded style connector. The device is used in general medicine in clinical, hospital, or other settings of healthcare professionals.

The Sterile Syringes for Single Use have different specifications, include1ml, 3mL , 5ml, 10ml, 20ml and 30ml.

7. Identification of predicate device

510(k) Number: K103736

Product name: DMC Medical Single-use Polycarbonate Syringe

7.1 Technological Comparison Table with the predicate

Table 3-1 Technological Comparison Table

Items	Proposed device	Predicate device K103736	Comment
Indications for Use	Sterile Syringes for Single Use are sterile, single-use, disposal, without needle and manually operated syringes intended to use with a 6% conical fitting device for injection of drug into the body. The syringes are intended for use immediately after filling and are not intended to contain the fluid/medication for extended periods of time.	DMC Medical piston type syringes are single use syringes, intended for injecting fluids into or withdrawing fluids from the body.	Similar Please see Comment 1
Description of Submitted Device	Sterile syringes for single use are composed of barrel, plunger, and a moveable piston. The plunger does	DMC Medical Sing-Use Polycarbonate Syringe is offered in the same configurations as the	Same

	not contact any part of the fluid path, rather the plunger which attaches to the piston and the barrel are fluid path components. Individual components are made from properly tested materials included in this submission. Additionly, there is a small amount of lubricant for moving the plunger smoothly along the inside surface of barrel. The connector is a universal luer threaded style connector. The device is used in general medicine in clinical, hospital, or other settings of healthcare professionals.	predicate. It is made from a calibrated hollow barrel, and a moveable piston with a plunger tip at the end of the piston. The piston shaft does not contact any part of the fluid path, rather the tip which attaches to the shaft and the barrel are fluid path components. Individual components are made from properly tested materials included in this submission. Additionally, there is a small amount of lubricant for moving the piston shaft smoothly along the inside surface of barrel. The connector is a universal luer threaded style connector. The device is used in general medicine in clinical, hospital, or other settings of healthcare professionals.	
Component and Materials: Syringe Barrel Plunger tip Silicone Oil Calibrated Barrel Volume Sterilization method 510(k) Approval	 Polycarbonate Polyisoprene rubber Medical Grade Oil(DC 360) YES EtO This submission	 Polycarbonate Polyisoprene Medical Grade Oil YES EtO K103736	Same
Principle of Operation	Sterile Syringes for Single Use, the user connects the syringe via the threaded luer, then manually advancing or withdrawing the plunger internal to the barrel, is able to express or withdraw fluids. Fluids are measured via the printed external scale of the barrel; measurements are indicated in ml(milliliters).	The user connects the syringe via the threaded luer, then manually advancing or withdrawing the plunger internal to the barrel, is able to express or withdraw fluids. Fluids are measured via the printed external housing of the barrel; measurements are indicated in ml(milliliters). operation is similar for most	Same

		all piston syringes whether fitted with a threaded luer or a slip-fit only end.	
Safety and Performances	Conforms to ISO 7886-1:2017. SAL:10^{-6} Complies with: ISO 10993-1: Evaluation and Testing; Part 4: Selection of tests for interactions with blood; Part 5: Tests for in vitro cytotoxicity; Part 7: Ethylene oxide sterilization residuals; Part 10: Tests for irritation and delayed type hypersensitivity; Part 11: Tests for systemic toxicity, tests for Bacterial endotoxins, Tests for Pyrogenicity And Conforms to USP <788>: Particulate Matter for injection No re-use	DMC Medical syringes conform to the requirements of ISO 7886-1, an FDA recognized standard. Additionally, the Sterility Assurance Level, (SAL) has been established to meet the 10^{-6} level. The single use syringes are packaged in a way as to ensure conformity with ISO 10993-1, including minimizing residual gases as well as discourage re-use.	Similar Please see comment 2.
Length (mm)	1ml: 86.6±0.5 3ml: 80.85±0.5 5ml: 83.5±0.5 10ml: 88.45±0.5 20ml: 96.4±0.5 30ml: 106.8±0.5	Not Clear.	Difference Please see comment 3.
Diameter(mm)	1ml: OD:9.45±0.1 ID: 4.7±0.1 3ml: OD:11.7±0.1 ID: 9.13±0.1 5ml: OD: 15.5±0.1 ID:12.83±0.1 10ml: OD: 19.45±0.1	Not Clear.	Difference Please see comment 4.

	ID: 16.45±0.1 20ml: OD: 22.9±0.1 ID: 19.9±0.1 30ml: OD: 26.2±0.1 ID: 23.7±0.1		
Size of Syringes(ml)	1, 3, 5, 10, 20, 30	Not Clear.	Difference Please see comment 5.
Luer Lock	ISO 80369-7	ISO 594-2	Difference Please see comment 6.
Prescription (Rx) or over the counter	Prescription	Prescription	Same

SE Comment 1: Indications for Use

The proposed device and the predicate device have same indication, that is, they are both intended for injecting fluid into body. But, the predicate device(K103736) has an additional indication, intended for withdrawing fluid from body The proposed device doesn't have this indication. However, the operation principle is same to achieve the indication. Therefore, the difference will not raise new questions on safety and effectiveness of the proposed device and substantially equivalence to the predicate.

SE Comment 2: Safety and Perform

The proposed device and the predicate device have the same test standard for ISO 7886-1 and ISO 10993-serious. But, the proposed device has different models and has added <USP 788> testing. However, all models are tested in accordance with ISO 7886-1 and USP <788> is required for the injection particles to ensure the safe clinical application. Therefore, this difference is considered not to affect the Substantially Equivalency (SE) between the proposed and predicate devices.

SE Comment 3: Length

The proposed device and the predicate device have similar components (Barrel, Plunger, Plunger Stopper) and all comply with ISO 7886-1. However, the differences in dimensions between the proposed device and the predicate are not known. However, dimensional differences do not raise new or different questions of safety and effectiveness. In addition, all barrel lengths and other dimensions have been shown to comply with ISO 7886-1.

SE Comment 4: Diameter

The proposed device and the predicate device have similar components (Barrel, Plunger, Plunger Stopper) and all comply with ISO 7886-1. However, the differences in dimensions between the proposed device and the predicate are not known. However, dimensional differences do not raise new or different questions of safety and effectiveness. In addition, all barrel lengths and other dimensions have been shown to comply with ISO 7886-1.

SE Comment 5: Size of Syringes

The proposed device and the predicate device have similar components (Barrel, Plunger, Plunger Stopper) and all comply with ISO 7886-1. However, the differences in dimensions between the proposed device and the predicate are not known. However, dimensional differences do not raise new or different questions of safety and effectiveness. In addition, all barrel lengths and other dimensions have been shown to comply with ISO 7886-1.

SE Comment 6: Luer Lock

The proposed device and the predicate device have similar components (Barrel, Plunger, Plunger Stopper) and all comply with ISO 7886-1 However, the differences in test standard for Luer Lock between the proposed device and the predicate are different, the predicated device have finished 510(K) in 2010 and the Luer lock have been tested in accordance with ISO 594-2, but ISO 594-2 was replaced by ISO 80369-7. However, standard number difference does not raise new or different questions of safety and effectiveness.

8. Non-clinical test conclusion

A. Performance testing was validated using the following Standard:

- ISO 7886-1:2017 Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications – Part 7 : Connectors for intravascular or hypodermic applications.

B. Biocompatibility

The device described in this summary the Sterile Syringe for Single Use were tested and demonstrated to be in conformance to ISO 10993-1 and FDA Guidance “Use of International Standard ISO 10993-1 “Biological evaluation of Medical Devices -Part 1 : Evaluation and Testing within a risk management process”. The proposed device is external communicating, blood path indirect, limited <24hr contact duration.

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemolysis

Particulate Testing using USP <788> Particulate Matter in Injection

C. Sterilization, Shipping, Shelf-life

The proposed device was evaluated for sterility using ISO 11135-Sterilization of healthcare products- Ethylene Oxide -Requirements for the for the development, validation and routine control of a sterilization process for medical devices

- Packaging Integrity Testing – ASTM F88/F88M-15 and ASTM F1929-15
  - Seal Strength – ASTM F00-09
  - Dye Penetration- ASTM F1929
- Simulated Shipping- ISTA 3A:2018

- Shelf-life of 5 years validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

9. Clinical test conclusion

No clinical study is included in this submission.

10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device, Sterile Syringes for Single Use are as safe, as effective, and are therefore substantially equivalentto the legally marketed predicate device DMC Medical Single-use Polycarbonate Syringe(K103736).