August 16, 2023

Shanghai Kindly Enterprise Development Group Co., Ltd
% Evan Hu
Technical and Regulatory Director
Shanghai Mind-link Consulting Co., Ltd.
1399 Jiangyue Road, Minhang
Shanghai, 201114
China

Re: K230447
Trade/Device Name: Sterile Syringe Convenience Tray
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: July 13, 2023
Received: July 17, 2023

Dear Evan Hu:

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: 2023.08.16 12:19:07 -04'00'

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230447

Device Name
Sterile syringe bulk tray

Indications for Use *(Describe)*
Sterile syringe bulk tray is sterile, single-use, and bulk packaged syringes for liquid aspiration and injection procedures.

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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K230447 510(k) Summary

1. **Preparation date: 08/03/2023**

2. **Submitter**

Manufacturer: Shanghai Kindly Enterprise Development Group Co., Ltd.
Address: No.658 Gaochao Road, 201803, Shanghai, China
Contact person: Liu Hualong, 86-02169118232, henry_liu@kdlchina.net
Submission correspondent: Evan Hu, 86-18616124827, evan.ww.hu@outlook.com

3. **Device**

Trading name: Sterile syringe bulk tray
Common name: Syringe
Regulation No.: 21 CFR 880.5860
Classification name: Syringe, Piston
Classification: Class II
Product code: FMF

4. **Predicate device**

Predicate device: K222124- Sterile Hypodermic Syringe with/without Needle

5. **Device description**

The sterile syringe bulk tray is designed for manual and single use. It includes multiple syringes and a bulk tray. Each syringe consists of a barrel, plunger, and plunger stopper (piston). The barrel and plunger are made from polypropylene, while the plunger stopper is made from Isoprene rubber. The device is available in different syringe volumes and offers both Luer slip (1mL) and Luer lock (1, 3, 5, 10, 20, 30, 50, 60mL) connectors. The Luer connector is used to connect the syringe to a hypodermic needle for liquid injection or withdrawal.
The medical device is enclosed in a thermal-formed plastic tray that is protected by dialyzing paper. It is sterilized using EO gas to ensure a shelf life of 5 years. The bulk tray packaging of the device is advantageous for performing batch liquid injections or withdrawals.
In order to maintain sterility, it is advised to utilize the device within 5 hours after the bulk tray has been opened. This device is specifically designed for application in aseptic environments and should only be handled by medical professionals.

6. Indications for use/Intended use

Sterile syringe bulk tray is sterile, single-use, and bulk packaged syringes for liquid aspiration and injection procedures.

7. Comparison of technological characters between proposed and predicate devices

Table 1. Characters comparison

Items	Proposed device (K230447-Sterile syringe bulk tray)	Predicate device (K222124- Sterile Hypodermic Syringe with/without Needle)	Comments
Indications for use/Intended use	Sterile syringe bulk tray is sterile, single-use, and bulk packaged syringes for liquid aspiration and injection procedures.	The Sterile Hypodermic Syringe with/without needle is intended for use in the aspiration and injection of fluids for medical purposes.	Different #1
Product code	FMF	FMF, FMI	Different #2
Prescription Use Only or Over the Counter	Prescription Use Only	Prescription Only	Same
Syringe configuration and materials used	-Barrel: Polypropylene -Plunger: Polypropylene -Stopper: Isoprene rubber -Lubricant agent: silicone oil	-Barrel: Polypropylene -Plunger: Polypropylene -Stopper: Isoprene rubber -Lubricant agent: silicone oil	Same
Syringe connection type	Luer Lock/Luer Slip	Luer Lock/Luer Slip	Same
Syringe volume	1, 3, 5, 10, 20, 30, 50, 60 mL	1, 2, 2.5, 3,5, 10, 20, 30, 50, 60, 100 mL	Different #3
Package type	Plastic tray covered with dialyzing paper	Tyvek pouch pack	Different #4
Use scenario	Batch injection preparation for patients in an aseptic environment to maintain sterility	Single injection preparation for patients in common clinical environment	Different #5
Sterilization	EO gas SAL: 10^{-6}	EO gas SAL: 10^{-6}	Same
Biocompatibility	Complied with ISO 10993-1 -Cytotoxicity -Irritation -Sensitization	Complied with ISO 10993-1 -Cytotoxicity -Irritation -Sensitization	Same

	-Systemic toxicity -Hemolysis -Pyrogen	-Systemic toxicity -Hemolysis -Pyrogen	
Syringe performance testing	Complied with the following standards: -ISO 7886-1 -ISO 80369-7 -ISO 80369-20	Complied with the following standards: -ISO 7886-1 -ISO 80369-7 -ISO 80369-20	Same

Comments:

#1:

The indications for uses are similar. The proposed and predicate devices are all intended for fluid aspiration and injection by connecting with needles.

However, the predicate device has the device configuration of syringes with needles and syringes without needles. Herein, only the configuration of syringes without needles is compared.

The difference is derived from the proposed device's package type containing several syringes in one pack. The package validation results demonstrated the bulk package type did not affect the device's safety.

In conclusion, the minor differences in indications for use don't impact the device's safety and effectiveness as a syringe, demonstrating substantial equivalence.

#2:

As mentioned in #1, only the syringe part is compared. Needles are not used for comparison in this submission. The primary product code is the same-FMF that represents the syringes. So, it doesn't impact the device's safety and effectiveness, demonstrating substantial equivalence.

#3:

The proposed device has a narrower syringe volume range than the predicate device, which is within the syringe volume range of the predicate device. Meanwhile, the performance testing results met the requirements of the standards (ISO 7886-1:2017 and ISO 80369-7:2016), demonstrating substantial equivalence.

#4:

As mentioned in #1, package validation results showed that the plastic tray package doesn't impact the device's safety and effectiveness, demonstrating substantial equivalence.

#5

The proposed device is designed for use in an aseptic environment for batch injection/withdrawal preparation. In contrast, the predicate device is intended for use in a standard clinical environment. The distinction between the two devices is based on packaging type. Therefore, a sterility test was conducted on the proposed device to demonstrate its sterility upon package opening, demonstrating substantial equivalence.

8. Non-clinical testing

PERFORMANCE TESTING

The proposed device was tested in compliance with ISO 7886-1:2017 for evaluating the overall non-clinical performance. Besides, Luer connector testing in compliance with ISO 80369-7:2016 and ISO 80360-20:2015 was conduct for evaluating the performance of connection to hypodermic needle. The performance and design testing results met the standards' requirements to demonstrate the device's safety and effectiveness.

The items listed below underwent testing in accordance with ISO 7886-1.

- Limits for extractable metals
- Limits for acidity or alkalinity
- Lubricant
- Tolerance on graduated capacity
- Conical fitting in accordance with ISO 80369-7
- Position of nozzle on end of barrel
- Scale
- Numbering of scales
- Overall length of scale to nominal capacity line
- Position of scale
- Barrel flanges
- Plunger stopper/plunger assembly
- Dead space
- Freedom from air and liquid leakage past plunger stopper
- Force to operate the piston
- Fit of plunger stopper/plunger in barrel

BIOCOMPATIBILITY TESTING:

The proposed device was tested in compliance with the 2020 FDA Guidance document Use of International Standard ISO 10993-1 “Biological Evaluation of Medical Devices - Part 1: Evaluation

and Testing within a Risk Management Process", as the Externally Communicating Device, Blood Path Indirect, Limited Contact (< 24hrs).
The items listed below underwent testing in accordance with ISO 10993-1.

- Cytotoxicity
- Irritation
- Sensitization
- Systemic toxicity
- Hemolysis
- Pyrogen

Meanwhile, Residual particles and Endotoxin were tested in compliance with USP <788> and USP <85>, respectively.

STERILE, PACKAGE AND SHELF-LIFE:
The sterilization process of the proposed device has been validated in compliance with ISO 11135. The EO and ECH residuals doesn't exceed the limit according to ISO 10993-7.
The Shelf-Life validation study was conducted under accelerated aging condition in compliance with ASTM F1980-16 to verify the claimed shelf-life of 5 years.
Package integrity testing under simulated shipping conditions was conducted to satisfy the requirements in ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems. All packaging was deemed acceptable for protection of product and sterility maintenance.
Sterile barrier testing was conducted in compliance with the following FDA recognized consensus standards.

- Seal Strength ASTM F88/F88-15
- Dye penetration ASTM F1929-15
- Sterility USP <71>

9. Clinical testing

Not applicable for this submission**.**

10. Conclusion

The differences between the predicate and the proposed device do not raise any new or different questions of safety or effectiveness. The proposed device is substantially equivalent to the predicate device with respect to indications for use and technological characteristics.