March 2, 2022

Gemtier Medical (Shanghai) Inc.
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K212652
Trade/Device Name: Sterile Syringe with Fixed Safety Needle for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, QNQ, QNS
Dated: January 27, 2022
Received: January 31, 2022

Dear Diana Hong:

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,

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)*
K212652.

Device Name
Sterile Syringe with Fixed Safety Needle for Single Use

Indications for Use *(Describe)*
Sterile Syringe with Fixed Safety Needle for Single Use is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately to minimize risk of accidental needlesticks.

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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K212652.510(k) Summary

1. Date of Preparation: March 2, 2022

2. Sponsor Identification

Gemtier Medical (Shanghai) Inc.

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Sterile Syringe with Fixed Safety Needle for Single Use

Regulatory Information
Classification Name: Piston Syringe
Classification: II;
Product Code: MEG, QNQ, QNS
Regulation Number: 21CFR 880.5860
Review Panel: General Hospital;

Indication for Use:
Sterile Syringe with Fixed Safety Needle for Single Use is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately to minimize risk of accidental needlesticks.

Device Description:
Sterile Syringe with Fixed Safety Needle for Single Use is intended for manual and single use only to aspirate and inject of fluids for medical purpose, which consists of syringe and fixed needle with a safety mechanism. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.

The proposed device is available in a variety combination of syringe volume and needle size.

Syringe volume	Needle Gauge	Length	Wall type
1ml	21G	5/8", 1"	TW
1ml	22G	5/8", 1"	TW
1ml	23G	5/8", 1"	TW
1ml	25G	5/8", 1"	RW

5. Identification of Predicate Device and Reference Device
Predicate 510(k) Number: K192679
Predicate Product Name: Sterile Syringe with Safety needle for Single Use

Reference Devices
Reference Device 510(k) Number: K210443
Reference Device Product Name: PLPT LDV (Low Dead Volume) Sterile Syringe

Reference Device 510(k) Number: K210444
Reference Device Product Name: EZ-Injec LDV Sterile Safety Needle

6. Technological Characteristic

The table below includes a comparison of the Technological characteristics between the new device and those of the predicate.

Table 1 Comparison of Technology Characteristics

ITEM	**Predicate Device** Sterile Syringe with Safety needle for Single Use K192679	**Subject Device** Sterile Syringe with Fixed Safety Needle for Single Use K212652	Comments
Regulation No.	21CFR 880.5860	21CFR 880.5860	Same
Product Code	MEG	MEG, QNQ, QNS	Comment 6
Class	II	II	Same
Indication for Use	Sterile Syringe with Safety needle for Single Use is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately after use to minimize risk of accidental needlesticks.	Sterile Syringe with Fixed Safety Needle for Single Use is intended for use in the aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety mechanism can be manually activated to cover the needle immediately to minimize risk of accidental needlesticks.	Same
Configuration	Barrel Plunger Piston Needle cap Needle tube Retractable cartridge Jointing medium Needle hub	Barrel Plunger Piston Needle cap Needle tube Retractable cartridge Jointing medium	See comment#1
Operation Mode	For manual use only	For manual use only	Same
Safety Feature	The needle is withdrawn into safety mechanism, the safety mechanism is fixed via latch lock to prevent arbitrary moving.	The needle is withdrawn into safety mechanism, the safety mechanism is fixed via latch lock to prevent arbitrary moving.	Same
Label/labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Single Use	Single Use	Single Use	Same
Syringe Volume	1ml, 2ml, 5ml, 10ml, 20ml, 30ml, 50ml	1ml	See comment#2
Needle Gauge	18G, 21G, 22G, 23G, 25G	21G, 22G, 23G, 25G	See comment#3
Needle Length	Available in 3/8'', 1/2", 5/8", 3/4", 1", 1 1/4", 1 1/2"	Available in 5/8", 1"	See comment#3
Wall Type	TW	TW, RW	See comment#4
Bevel Design	Long bevel, bevel angle: 13°	Long bevel, bevel angle: 13°	Same
Maximum low dead space volume specification	<0.07ml	<0.015mL	See comment#6
Performance Test	Complied with ISO 7886-1, ISO 7864 ISO 9626 ISO 80369-7	Complied with ISO 7886-1, ISO 7864, ISO 9626	See comment#5
Material			
Barrel	Polypropylene (PP)	Polypropylene (PP)	See comment#7
Plunger	Polypropylene (PP)	Polypropylene (PP)	
Piston	Polyisoprene	Polyisoprene	
Needle tube	Stainless steel (SUS304)	Stainless steel (SUS304)	
Needle cap	Polypropylene (PP)	Polypropylene (PP)	
Jointing medium	Methyl methacrylate acrylonitrile butadiene styrene (MABS)	Acrylonitrile butadiene styrene (ABS)	
Outer retractable cartridge	Polycarbonate (PC)	Polycarbonate (PC)	
Middle retractable cartridge	Polycarbonate (PC)	Polycarbonate (PC)	
Inner retractable cartridge	Polycarbonate (PC)	Polycarbonate (PC)	
Lubricant	Silicon plastic agent	Silicon plastic agent	
Adhesive	UV Light Cure Adhesive	UV Light Cure Adhesive	
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	

Pyrogen	No Pyrogen	No Pyrogen	
Complement Activation	Not show potentials to activate complete system	Not show potentials to activate complete system	
In vivo Thrombogenicity	No thrombogenicity	No thrombogenicity	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20EU	20EU	Same

Discussion of differences in Technological characteristics

Comment 1- Configuration

The configuration between proposed device and predicate device is different. However, the basic configurations are same, both of them include barrel, plunger, piston, needle, needle cap, retractable cartridge and jointing medium. The only different is that the proposed device has a fixed needle, so there is no needle hub. Whether there is a needle hub does not affect the use of the device. Therefore, the difference on configuration will not raise new questions on safety and effectiveness of the proposed device.

Comment 2- Syringe Volume

The syringe volume for proposed device is covered by predicate device syringe volume. This difference will not raise new questions on safety and effectiveness of the proposed device.

Comment 3-Needle Gauge and Needle Length

The needle gauge and needle length of predicate device is more than proposed device, and for proposed device, the needle gauge and needle length are covered by predicate device. This difference will not raise new questions on safety and effectiveness of the proposed device.

Comment 4-Wall Type

The wall type between proposed device and predicate device is different, the proposed device has two wall types: normal wall and thin wall, while the predicate device only has thin wall. This difference will not raise new questions on safety and effectiveness of the proposed device.

Comment 5-Performance Test

The proposed device is syringe with fixed needle, so the ISO 80369-7 connector test of proposed device is not applicable. This difference will not raise new questions on safety and effectiveness of the proposed device.

Comment 6-Maximum low dead space volume specification

The maximum low dead space volume specification of predicate device is greater than proposed device. Smaller dead cavities have smaller residues, resulting in less fluid loss. In addition, the dead space volume has been evaluated and test results comply with ISO 7886. Therefore, this difference will not raise new questions on safety and effectiveness of the proposed device.

The dead volume specification is comparable to the reference devices' dead volume specifications (syringe and needle combined dead space) and were used as a reference value for adding the QNQ and QNS product codes. Performance data supported the specification of <0.015 mL maximum dead space.

Comment 7- Material

The material for the propose device is different from predicate device. This difference will not raise new questions on safety and effectiveness of the proposed device.

7. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The testing included the following items:

Physical, Mechanical, Chemical testing listed in following table were performed on the proposed device. The test results show that the device conforms with the requirements of related standards.

Table 2 Performance Testing

Test	STANDARD
Needle Performance	ISO7864:2016 Fourth edition; Sterile hypodermic needles for single use- Requirements and Test methods ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices- Requirements and test methods.
Syringe Performance	ISO 7886 Second edition: Sterile Hypodermic syringes for single use- Syringes for manual use.
Sharp Injury Protection	ISO 23908 First edition: Sharps injury protection-Requirements and test methods -Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Simulated Clinical Study

A simulated clinical study was performed on proposed device according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005 and ISO 23908:2011 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

Safety Feature Test

The safety feature test was performed on both proposed device and predicate device to determine its safety feature. The results demonstrated that both the proposed device and predicate device meet the acceptance criteria.

Biocompatibility testing

In accordance with ISO10993-1 the syringe and needle are classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (< 24hrs). The following testing was conducted:

- Cytotoxicity
- Irritation
- Skin Sensitization
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

Particulate matter testing was conducted in accordance with USP<788>Particulate Matter in Injection and met the USP acceptance criteria.

Sterility, Shipping, and Shelf -life

The proposed device sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels were below the level of 20 EU/device in accordance with USP <85>. Both baseline and accelerated shelf life testing were conducted demonstrating the device will perform as intended to support the proposed 3 year shelf-life.

- Package integrity test – after environmental conditioning, simulated transportation testing in accordance to ASTM D4169-16 on final, packaged, and sterile device.
- Sterile Barrier Packaging performed on the proposed device:
  - Seal Strength ASTM F88/F88-15
  - Dye penetration ASTM F1929-15
- Shelf-life of 3-years is validated using FDA recognized standard ASTM F 1980 -16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Sterile Syringe with Fixed Safety Needle for Single Use is substantially equivalent to the Sterile Syringe with Safety needle for Single Use with respect to the indications for use, target populations, treatment method, and technological characteristics.