October 27, 2023

Shina Med Corporation
% Peter Chung
President
Plus Global
300, Atwood street
Pittsburgh, Pennsylvania 15213

Re: K231165
Trade/Device Name: Shina Syringe; Shina Safety Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: September 22, 2023
Received: September 22, 2023

Dear Peter Chung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Juliane C. Lessard -S

Juliane C. Lessard, Ph.D.
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)*

K231165

Device Name
Shina Syringe, Shina Safety Syringe

Indications for Use *(Describe)*
Shina Syringe, Shina Safety Syringe is a plastic sterile syringe and hypodermic single lumen needle intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

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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510(k) Summary

1. Applicant

1) Company : Shina Med Corporation
2) Address : 455-30. Bogaewonsam-ro, Anseong-si, Gyeonggi-do, Republic of Korea
3) Tel : 82-31-8057-2125
4) Fax :
5) Prepared date : 10/16/2023
6) Contact person : Peter Chung, 412-512-8802
7) Contact person address : 300, Atwood Street, Pittsburgh, PA, 15213, USA
8) Submission date : Apr. 25, 2023

2. Device Information

1) Trade name : Shina Syringe, Shina Safety Syringe

1) Common name : Piston syringe
2) Regulation name : Syringe, Antistick
3) Product code : MEG / FMF, FMI
4) Regulation number : 21 CFR 880.5860
   21 CFR 880.5570
5) Class of device : Class II
6) Panel : General Hospital

3. The legally marketed device to which we are claiming equivalence

K210443, Poonglim Pharmatech Inc. / PLPT LDV (Low Dead Volume) Sterile Syringe
K210444, Poonglim Pharmatech Inc. / EZ-Injec LDV Sterile safety Needle

4. Device description

A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both); a needle is (not) included. It is intended for various medical applications and is not dedicated to medication administration. At the distal end of the barrel is a male connector (typically Luer-lock/slip type) for the attachment to a hypodermic needle or an administration set. It is typically made of plastic and silicone materials and may have anti-stick plunger allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.

5. Intended Use

Shina Syringe, Shina Safety Syringe is a plastic sterile syringe and hypodermic single lumen needle intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

6. Performance data:

1) Bench test were performed. Bench testing included biocompatibility and mechanical testing. The tests demonstrated that the device performs in a substantially equivalent manner to the predicate device. The following bench testing is performed to demonstrate the functionality is substantially equivalent.

Syringe

Test item	**Reqirements**
Appearance and Structure	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Graduated capacity	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Scale	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Barrel	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Plunger stopper / Plunger assembly	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use

Nozzle	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Dead Space	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Freedom from liquid leakage past plunger stopper	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Freedom from air leakage past plunger stopper	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Force to operate the piston	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Fit of plunger stopper / plunger in barrel	ISO 7886-1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
Amount of Silicon Oil	0.25mg or less per square centimeter of inner area
EO Gas residuals	ISO 10993-7:2008 Ethylene oxide sterilization residuals
Sterility test	EO, ECH residuals

Needle

Test item	**Requirements**
Cleanliness	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Size designation	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Colour coding	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Needle hub	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Needle tube (Tolerances on length)	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Freedom from defects	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Lubricant	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Needle point	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Bond between hub and needle tube	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Patency of lumen	ISO 7864:2016 Sterile hypodermic needles for single use – Requirements and test methods
Sharps injury protection	ISO 23908:2011 Sharps injury protection
Materials	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
Surface finish and visual appearance	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
Cleanliness	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
Limits for acidity and alkalinity	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
Size designation	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
Dimension	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
Stiffness	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
Resistance to breakage	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods
Resistance to corrosion	ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices – Requirements and test methods

Syringe with needle (Model : WNLS0125)

Test item	**Requirements**
Extraction : pH	Difference of pH ≤ 1.0
Extraction : Potassium permanganate reducing	Difference of the consumption ≤ 2.0 mL

substances	
Extraction : Residue on evaporation	Amount of residue ≤ 1.0 mg
Extraction : Pb, Fe, Sn, Zn	Total content of heavy metals ≤ 5.0 mg/L
Extraction : Cd	Content of Cd ≤ 0.1 mg/L

Syringe with needle (Model : WNLG0123, WNLS0123, WNSG0125, WNLS0125)

Test item	**Requirements**
Particulate test report	USP <788> Method 1. Light obscuration method

Syringe with needle (Model : WNLG0323, WNLS0323, WNSG0325, WNLS0325)

Test item	**Requirements**
Particulate test report	USP <788> Method 1. Light obscuration method

Syringe with needle (Model : WNLG0523, WNLS0523, WNSG0525, WNLS0525)

Test item	**Requirements**
Particulate test report	USP <788> Method 1. Light obscuration method

Syringe with needle (Model : WNLG1023, WNLS1023, WNSG1025, WNLS1025)

Test item	**Requirements**
Particulate test report	USP <788> Method 1. Light obscuration method

Safety test with ISO 23908

Test item	**Requirements**
Simulated Clinical Use	ISO 23908:2011 Sharps injury protection

2) Biocompatibility

25G Model (Model : SSN2501)

#	Test item	Test method / Test criteria
1	Cytotoxicity	ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2	Acute systemic toxicity test	ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
3	Pyrogen test	ISO 10993-11:2017 Test for systemic toxicity, pyrogen test USP <151>
4	Sensitization test	ISO 10993-10:2010 Biological evaluation of medical devices – Part 10 Tests for irritation and skin sensitization
5	Hemolytic test	ISO 10993-4:2017, ASTM F756-17
6	Intracutaneous reactivity test	ISO 10993-23 :2021 Biological evaluation of medical devices – Part 23 Tests for irritation

23G Model (Model : SSN2301)

#	Test item	Test method / Test criteria
1	Cytotoxicity	ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2	Acute systemic toxicity test	ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
3	Pyrogen test	ISO 10993-11:2017 Test for systemic toxicity, pyrogen test USP <151>
4	Sensitization test	ISO 10993-10:2010 Biological evaluation of medical devices – Part 10 Tests for irritation and skin sensitization
5	Hemolytic test	ISO 10993-4:2017, ASTM F756-17
6	Intracutaneous reactivity test	ISO 10993-23 :2021 Biological evaluation of medical devices – Part 23 Tests for irritation

Syringe (Model : SSN2301)

#	Test item	Test method / Test criteria
1	Cytotoxicity	ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2	Acute systemic toxicity test	ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
3	Pyrogen test	ISO 10993-11:2017 Test for systemic toxicity, pyrogen test USP <151>
4	Sensitization test	ISO 10993-10:2010 Biological evaluation of medical devices – Part 10 Tests for irritation and skin sensitization
5	Hemolytic test	ISO 10993-4:2017, ASTM F756-17
6	Intracutaneous reactivity test	ISO 10993-23 :2021 Biological evaluation of medical devices – Part 23 Tests for irritation

The performance tests demonstrated that the subject device performs in a substantially equivalent manner to the predicate device.

7. Predicate device comparison table

Manufacturer	Shina Med Corporation	Poonglim Pharmatech Inc.	Poonglim Pharmatech Inc.	Remark
510(k) No.		K210443	K210444	N/A
Indication for use	Shina Syringe, Shina Safety Syringe is a plastic sterile syringe and hypodermic single lumen needle intended to be used for medical purpose to inject fluid into or withdraw fluid from body.	PLPT LDV (Low Dead Volume) Sterile Syringe is intended to be used for medical purpose to inject fluid into or withdraw fluid from body.	This produce is intended for use to inject fluid into or withdraw fluids from parts of the body below the surface of the skin.	Identical
Classification name	Syringe, Antistick	Low Dead Space Piston Syringe	Low Dead Space Needle, Single Lumen, Hypodermic	Different
Trade name	Shina Syringe, Shina Safety Syringe	PLPT LDV (Low Dead Volume) Sterile Syringe	EZ-Injec LDV Sterile Safety Needle	N/A
Model/type	40 Models including WOS01	-	-	N/A
Components	Needle, Hub, Safety cover, Barrel, Gasket, Plunger	Barrel, Gasket, Plunger	Needle, Hub, Safety cover	Identical
Nozzle type	Lock and Slip type	Lock type	Lock and Slip type	Identical
Materials Needle Hub Safety cover Barrel Gasket Plunger	 Stainless Steel PP PP PP Hydrogenated styrene isoprene butadiene block copolymer PP	 PP Rubber PP	 Stainless Steel PP PP	Different
Capacity	1mL, 3mL, 5mL, 10mL	1mL	-	Different
Needle Gauge	23G, 25G	-	25G	Different
Needle Length	25.4mm	-	25mm	Different
Sharps Function	Safety Guard	-	Safety Guard	Identical
Principle of operation	Manual	Manual	Manual	Identical
Performances	ISO 7886 ISO 7864 ISO 9626 USP <788> ISO 23908	ISO 7886	ISO 7864 ISO 9626 ISO 23908 USP <788>	Identical

Manufacturer	Shina Med Corporation	Poonglim Pharmatech Inc.	Poonglim Pharmatech Inc.	Remark
Biocompatibility	Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Hemolysis Intracutaneous test	Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Hemocompatibility	Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Hemocompatibility	Identical
Sterilization Method	EO gas	EO gas	EO gas	Identical
Populations	Adults and Pediatrics	Adults and Pediatrics	Adults and Pediatrics	Identical
Dead space	Meets ISO 7886-1 standard	Less than 0.0023mL with 95% confidence and 95% reliability	Less than 0.0054mL with 95% confidence and 95% reliability	Different

1. Different classification name
   We set K210443 and K210444 as predicate devices. The product code is set differently to MEG for subject device and QNS and QNQ for predicate device respectively. However, K210443 and K210444 were set as predicate devices because of the similarity in appearance and purpose of use of needles and syringes with safety features.

2. Different syringe capacity
   The volume of the syringe is 1mL for the predicate device and 1mL, 3mL, 5mL and 10mL for the subject device. Syringes with a volume larger than 1 mL are not included in the range, but tests were performed that included each syringe under ISO 7886 standard.

3. Different needle gauge
   The gauge of the needle is 25G for the predicate device and 23G and 25G for the subject device. 23G needles are not included in the range, but both the 23G and 25G have been tested for performance under ISO 7864 and ISO 9626 standards.

4. Different needle length
   The needle of the subject device is 25.4mm while the needle length of the predicate device is 25mm. Through testing of ISO 7864 and ISO 9626, the needle length of the subject device has been evaluated for substantial equivalence.

5. Different materials
   All materials are not identical. Only gasket material is different. Subject device had been performed the biocompatibility tests according to ISO 10993 series to meet the toxicity endpoints.

6. Different dead space
   The subject device was tested to meet the dead space requirements of ISO 7886-1. The predicate device is a low dead volume syringe and needle while the subject device is not a low dead volume device. Although the subject device does not meet a lower dead space specification, it still meets the ISO 7886-1 recommendations to perform its intended use.

8. Conclusion

The device is investigated for function to compare the operation of function between Shina Syringe, Shina Safety Syringe and predicate devices.
Comparison results demonstrate that the specifications and performance of the device are substantially equivalent to the legally marketed predicate device.
Therefore, it is concluded that Shina Syringe, Shina Safety Syringe are substantially equivalent to the legally marketed predicate devices.