October 14, 2025

SHINA MED CORPORATION
℅ Peter Chung
President
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K250510
Trade/Device Name: Sure-Fine Insulin Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 21, 2025
Received: Septermber 15, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shruti N. Mistry -S

Shruti Mistry
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250510

Device Name
Sure-Fine Insulin Syringes

Indications for Use *(Describe)*
Sure-Fine Insulin Syringes are hypodermic insulin syringes for subcutaneous injection of U100 insulin.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K250510 510(k) Summary

1. Date of Preparation: September 15, 2025

2. Applicant

1) Company: SHINA MED CORPORATION
2) Address: 455-30, Bogaewonsam-ro Bogae-myun, Anseong-si, Gyeonggi-do, 17509, Republic of Korea
3) Tel : +82-31-8057-2125
4) Fax : +82-31-8057-2150
5) Contact person: Peter Chung, 412-512-8802
6) Contact person address: 300 Atwood Street, Pittsburgh, PA, 15213, USA

3. Subject Device Information

1) Trade name : Sure-Fine Insulin Syringes
2) Common name : Piston Syringe
3) Classification name : Syringe, Piston
4) Product code : FMF
5) Regulation number : 880.5860
6) Class of device : Class II
7) Panel : General Hospital

4. Predicate Devices

1) Predicate Submission Number: K210848 Sure-Fine Insulin Syringes
2) Manufacturer: SHINA MED CORPORATION

5. Device description

Sure-Fine Insulin syringes are designed for the subcutaneous injection of a desired dose of insulin. The syringe has a graduated barrel(U-100), a plunger rod, needle cap, protective end cap and needle permanently affixed to the tip of the syringe with epoxy.

The syringes are available in the following size and cap color.

Category	Insulin Syringe	Needle gauge	Needle length	Cap Color	
				Needle Cap	Protective end cap
U-100	1 cc	27 Gauge	1/2″	Orange	Orange or White
	1 cc	27 Gauge	5/16″		
	1/2cc and 1 cc	28 Gauge	1/2″		
	1/2cc and 1 cc	28 Gauge	5/16″		
	3/10cc, 1/2cc and 1 cc	29 Gauge	1/2″		
	3/10cc, 1/2cc and 1 cc	29 Gauge	5/16″		
	3/10cc, 1/2cc and 1 cc	30 Gauge	1/2″		
	3/10cc, 1/2cc and 1 cc	30 Gauge	5/16″		
	3/10cc and 1/2cc	30 Gauge	1/4″		
	3/10cc, 1/2cc and 1 cc	31 Gauge	5/16″		
	3/10cc and 1/2cc	31 Gauge	1/4″		

6. Indications for Use:

Sure-Fine Insulin Syringes are hypodermic insulin syringes for subcutaneous injection of U100 insulin.

7. Performance data:

1) Bench tests for the device's performance were conducted. The following bench testing is performed to demonstrate the functionality is substantially equivalent.

	Test items	Result
Needle (ISO 7864)	Cleanliness	Pass
	Size designation	Pass
	Tolerances on length	Pass
	Freedom from defects	Pass
	Lubricant	Pass
	Needle point	Pass
	Patency of lumen	Pass
	Bond between hub and needle tube	Pass
Needle (ISO 9626)	Materials	Pass
	Surface finish and visual appearance	Pass
	Cleanliness	Pass
	Limits for acidity and alkalinity	Pass
	Size designation	Pass
	Dimension	Pass
	Stiffness	Pass
	Resistance to breakage	Pass
	Resistance to corrosion	Pass
Syringe (ISO 8537)	Design of the plunger and push-button	Pass
	Fit of piston in barrel	Pass
	Liquid and air leakage past piston	Pass

2) Biocompatibility

Biocompatibility of the Sure-Fine Insulin Syringes was evaluated in accordance with ISO 10993-1:2018. The following tests were performed: Cytotoxicity; Skin sensitization; Hemocompatibility; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity; Sub-acute systemic toxicity. All evaluation acceptance criteria were met.

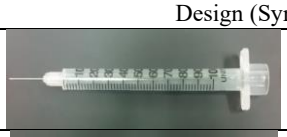
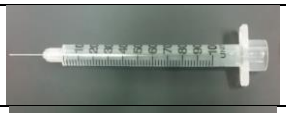
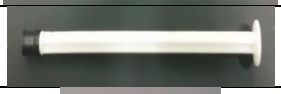
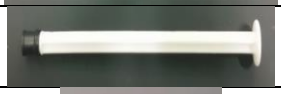
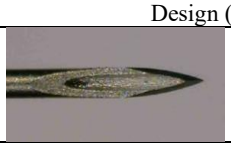
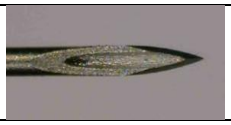
Test item	Test method / Test criteria	Test result
Cytotoxicity test	When it was tested according to ISO 10993-5, tests for in vitro cytotoxicity-Test on extracts method, it should satisfy the requirements.	Pass
Hemolysis test	When it was tested according to ISO 10993-4, Selection off tests for interactions with blood-evaluation of hemolytic properties of medical devices and medical device materials, it should satisfy the requirements.	Pass
Intracutaneous reactivity test	When it was tested according to ISO 10993-10, Tests for irritation and skin sensitization-Animal intracutaneous (Intradermal) reactivity test, it should satisfy the requirements.	Pass
Skin sensitization test	when it was tested according to ISO 10993-10, Tests for irritation and skin sensitization-Guinea pig maximization test (GPMT), it should satisfy the requirements.	Pass
Acute systemic toxicity test	When it was tested according to ISO 10993-11, Tests for systemic toxicity-Acute systemic toxicity, it should satisfy the requirements.	Pass
Pyrogen Test	When it was tested according to ISO 10993-11, Tests for systemic toxicity-Information on material-mediated pyrogens, it should satisfy the requirements.	Pass
Sub-acute systemic toxicity	When it was tested according to ISO 10993-11, Tests for systemic toxicity-Sub-acute systemic toxicity, it should satisfy the requirements.	Pass

8. Sterilization and Shelf-life Testing

Sterilization validation was performed in accordance with ISO 11135:2014 to prove that the E.O Gas sterilization process has been suitable for the continuous production. Through validation, sterilization process was deemed acceptable.

Also, the device's Shelf life of 5 years is validated in accordance with ISO 11607-1:2006 and ISO 11607-2:2006.

9. Substantially Equivalent (SE) Comparison

	Proposed device	Predicate device	Remark
Manufacturer	SHINA MED CORPORATION	SHINA MED CORPORATION	Same
510(K) No.	K250510	K210848	N/A
Trade Name	Sure-Fine Insulin Syringe	Sure-Fine Insulin Syringe	Same
Indication for use	Sure-Fine Insulin Syringes are hypodermic insulin syringes for subcutaneous injection of U100 insulin.	Sure-fine Insulin Syringes are hypodermic insulin syringes for subcutaneous injection of U100 insulin.	Same
Design (Syringe)			
Needle/Barrel			Same
Gasket/Plunger			Same
Needle cap			Same
Protective end cap			Same
Volume	0.3cc, 0.5cc, 1.0cc	0.3cc, 0.5cc, 1.0cc	Same
Design (Needle)			
Needle tip shape			Same
Gauge and Length	27G 1/2", 27G 5/16", 28G 1/2", 28G 5/16", 29G 1/2", 29G 5/16", 30G 1/2", 30G 5/16", 30G 1/4", 31G 5/16", 31G 1/4",	27G 1/2", 28G 1/2", 29G 1/2", 30G 1/2", 30G 5/16", 30G 1/4", 31G 5/16", 31G 1/4",	Different #1 : 27G 5/16", 28G 5/16",29G 5/16" are added
Raw Material			
Needle	STS304	STS304	Same
Barrel	Polypropylene	Polypropylene	Same
Plunger	Polypropylene	Polypropylene	Same
Piston	Hydrogenated styrene isoprene butadiene block copolymer compound (TPE)	Hydrogenated styrene isoprene butadiene block copolymer compound (TPE)	Same
Needle cap	Polypropylene	Polypropylene	Same
Protective end cap	Polypropylene	Polypropylene	Same
Silicon	Polydimethylsiloxane	Polydimethylsiloxane	Same
Biocompatibility	Conform ISO10993-1	Conform ISO10993-1	Same
Sterilization method	Sterilized by ethylene oxide gas SAL = 10^{-6}	Sterilized by ethylene oxide gas SAL = 10^{-6}	Same

Different 1 – Needle configuration (Length, gauge)

The overall configuration of SHINA MED Sure-Fine Insulin Syringe's needle component is the same as the configuration of predicate device. The difference is that proposed device has more variable needle configurations. However, the needle configuration is widely used in the clinical environment. Performance testing for the needle component was conducted in accordance with FDA recognized standard (e.g., ISO 7864, ISO 9626). The results demonstrate that needle configuration of proposed device conforms with the relevant standard. Therefore, the differences on configuration do not raise new questions about its safety and/or effectiveness when compared to the predicate device.

10. Substantially Equivalent (SE) Conclusion

Based on the information provided in this Special 510(k), the Sure-Fine Insulin Syringes are substantially equivalent to the predicate devices (K210848).