March 1, 2022

Shina Med Corporation
℅ Priscilla Chung
Regulatory Affairs Consultant
Lk Consulting Group USA, Inc.
1150 Roosevelt Ste 200
Irvine, California 92620

Re: K210848
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: January 24, 2022
Received: February 2, 2022

Dear Priscilla 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 (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)*
K210848

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.

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510(K) SUMMARY

(K210848)

Date: Feb 23, 2022

1. Submitted by:

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2. US Agent/ Official Correspondent:

Priscilla Chung

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3. Device Name:

- Trade Name : Sure-Fine Insulin Syringes
- Classification : Class II
- Classification Name : Piston syringe
- Product Code : FMF
- Regulation Number : 21 CFR 880.5860
- Review Panel : General Hospital

4. Predicate Device:

Sure-Fine Insulin Syringes (K191531) by 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 expoxy.

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
	1/2cc and 1 cc	28 Gauge	1/2″		
	3/10cc, 1/2cc and 1 cc	29 Gauge	1/2″		
	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″		

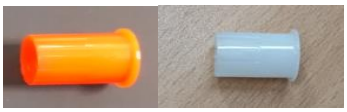
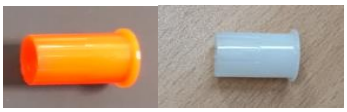
6 Indications for Use Statement

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

7 Substantial Equivalence Discussion:

The indications for use, labeling and all the other aspects are the same between the subject device and the cleared devices. The only difference is the gasket material.

Device Name		Subject Device	Cleared Device
Manufacturer		SHINA MED CORPORATION	SHINA MED CORPORATION
510(k) Number		K210848	K191531
Product Code		FMF	FMF
Intended 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.
Design (Syringe)	Needle / Barrel		

	Gasket / Plunger		
	Needle Cap		
	Protective end cap		
	Volume	0.3cc, 0.5cc, 1.0cc	0.3cc, 0.5cc, 1.0cc
Design (Needle)	Needle Tip shape		
	Gauge	27, 28, 29, 30,31Gauge	27, 28, 29, 30,31Gauge
	Length	1/2", 5/16", 1/4”	1/2", 5/16", 1/4”
Materials	Needle	STS304	STS304
	Barrel	Polypropylene	Polypropylene
	Plunger	Polypropylene	Polypropylene
	Piston	Hydrogenated styrene isoprene butadiene block copolymer compound (TPE)	Isoprene Rubber
	Needle Cap	Polyethylene	Polyethylene
	Protective end cap	Polyethylene	Polyethylene
	Silicon	Polydimethylsiloxane	Polydimethylsiloxane

Available Configurations	Category	Insulin Syringe	Needle Gauge	Needle Length	Cap Color		Category	Insulin Syringe	Needle Gauge	Needle Length	Cap Color	
					Needle Cap	Protective end cap					Needle Cap	Protective end cap
	U-100	1 cc	27 Gauge	1/2″	Orange(U-100)	Orange/White (U-100)	U-100	1 cc	27 Gauge	1/2″	Orange(U-100)	Orange/White (U-100)
		1/2cc and 1 cc	28 Gauge	1/2″				1/2cc and 1 cc	28 Gauge	1/2″		
		3/10cc, 1/2cc and 1 cc	29 Gauge	1/2″				3/10cc, 1/2cc and 1 cc	29 Gauge	1/2″		
		3/10cc, 1/2cc and 1 cc	30 Gauge	1/2″				3/10cc, 1/2cc and 1 cc	30 Gauge	1/2″		
		3/10cc, 1/2cc and 1 cc	30 Gauge	5/16″				3/10cc, 1/2cc and 1 cc	30 Gauge	5/16″		
		3/10cc and 1/2cc	30 Gauge	1/4″				3/10cc and 1/2cc	30 Gauge	1/4″		
		3/10cc, 1/2cc and 1 cc	31 Gauge	5/16″				3/10cc, 1/2cc and 1 cc	31 Gauge	5/16″		
		3/10cc and 1/2cc	31 Gauge	1/4″				3/10cc and 1/2cc	31 Gauge	1/4″		
Biocompatibility	Conform ISO10993-1						Conform ISO10993-1					
Sterilization method and S.A,L	Sterilized by ethylene oxide gas SAL = 10^{-6}						Sterilized by ethylene oxide gas SAL = 10^{-6}					

8. Technological Characteristics:

The Sure-fine insulin syringe and the predicate device have the substantially equivalent technological characteristics and perform as piston syringes. Risks associated with the changes were identified and appropriate design controls implemented to mitigate the risks.

Based on the change assessment, it is concluded that the risks are associated with the biocompatibility of the new gasket material and the performance. To mitigate risks, appropriate testing was completed to demonstrate that the syringes comply with the following FDA recognized standards:

No	Test	Standard
1	Cytotoxicity Test	ISO 10993-5
2	Animal intracutaneous Reactivity Test	ISO 10993-10
3	Guinea pig maximization test	ISO 10993-10
4	Acute systemic toxicity test	ISO 10993-11

5	Pyrogen test	ISO 10993-11, USP <151>
6	In-vitro hemolysis test	ISO 10993-4, ASTM F756-17
7	Shelf Life Performance Test	ASTM F1980, ISO 8537, ISO 7864

9. Conclusion:

Based on the information provided in this special 510(k), the Sure-fine insulin syringes are substantially equivalent to the previous devices (K191531).