September 6, 2019

Shina Med Corporation
Park Sung-Soon
Manager
455-30 Bogaewonsam-ro, Bogae-myun
Anseong-si, 456-871 KOREA

Re: K191531
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: August 6, 2019
Received: August 9, 2019

Dear Park Sung-Soon:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191531

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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"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."

510(K) SUMMARY – K191531

September 6, 2019

1. Submitted by :

Sung-soon, Park / Quality Management Representative

SHINA MED CORPORATION

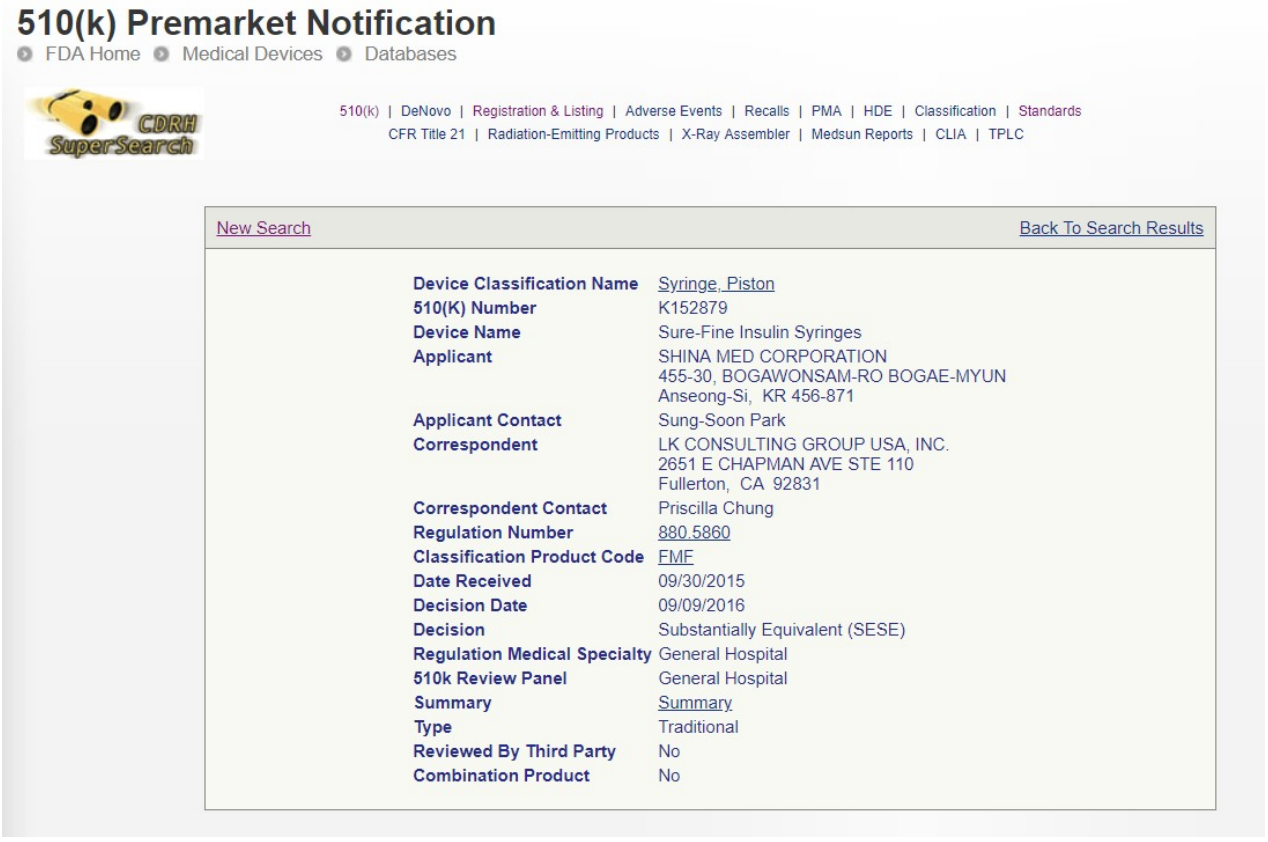
455-30, Bogaewonsam-ro Bogae-myeon, Anseong-si, Gyeonggi-do, 17509, Rep. of Korea

Phone : +82 31 8057 2125 Fax : + 82 31 8057 2150

2. 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

3. 510(k) Premarket Notification: K152879



510(k) Premarket Notification

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CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

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Device Classification Name	Syringe, Piston
510(K) Number	K152879
Device Name	Sure-Fine Insulin Syringes
Applicant	SHINA MED CORPORATION 455-30, BOGAWONSAM-RO BOGAE-MYUN Anseong-Si, KR 456-871
Applicant Contact	Sung-Soon Park
Correspondent	LK CONSULTING GROUP USA, INC. 2651 E CHAPMAN AVE STE 110 Fullerton, CA 92831
Correspondent Contact	Priscilla Chung
Regulation Number	880.5860
Classification Product Code	FMF
Date Received	09/30/2015
Decision Date	09/09/2016
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

4 Device Description:

4.1 Predicate Device Description(K152879)

Sure-fine Insulin syringes are designed for the subcutaneous injection of a desired dose of insulin.

The syringe has a graduated barrel, 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 sizes and cap color.

Category	Insulin syringe	Needle Gauge	Needle Length	Cap color	
				Needle cap	Protective cap
U-100	1/2cc and 1cc	28Gauge	1/2"	Orange	Orange or white
	3/10cc, 1/2cc and 1cc	29Gauge	1/2"	Orange	Orange or white
	3/10cc, 1/2cc and 1cc	30Gauge	1/2"	Orange	Orange or white

	3/10cc, 1/2cc and 1cc	30Gauge	5/16"	Orange	Orange or white
	3/10cc, 1/2cc and 1cc	31Gauge	5/16"	Orange	Orange or white

4.2 Device description for Special 510(k), K191531

The modified Sure-Fine Insulin syringe is substantially equivalent to the predicate device (Sure-Fine Insulin Syringes, K152879). The biggest difference between the modified device and predicate device is the addition of needle gauge (27G) and the addition of needle length (1/4").

The design features and sizing of the components were compared and the Sure-Fine Insulin Syringe is found to be substantially equivalent to the predicate device.
The similarity in design between modified Sure-Fine Insulin Syringes and the previous device supports the substantial equivalence of Sure-Fine Insulin Syringe for the indicated use.

Therefore, modified Sure-Fine Insulin Syringe is substantially equivalent to the previous device in terms of indications, compositions, material, design, safety and effectiveness.
The syringes are available in the following sizes and cap color.

Category	Insulin syringe	Needle Gauge	Needle Length	Cap color	
				Needle cap	Protective cap
U-100	3/10cc and 1/2cc	30Gauge	1/4"	Orange	Orange or white
	3/10cc and 1/2cc	31Gauge	1/4"	Orange	Orange or white
	1cc	27Gauge	1/2"	Orange	Orange or white

The devices operate in the principles of a piston syringe. the syringe fluid path is sterile (EO gas sterilization), Non-toxic, Non-pyrogenic and single use disposable.

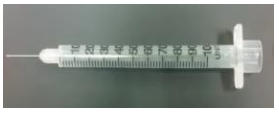
4.3 Substantial Equivalence Discussion

Modified Sure-Fine Insulin syringe is substantially equivalent to the predicate Sure-Fine Insulin Syringes device(K152879).

The design features and sizing of the components were also compared and the Sure-Fine

Insulin Syringe is substantially the same as the predicate device product.
The similarity in design between modified Sure-Fine Insulin Syringes and the previous device supports the safety and effectiveness of Sure-Fine Insulin Syringe for the indicated use.
The biggest difference between modified device and previous device is the addition of needle gauge (27G) and the addition of needle length (1/4").

Therefore, modified Sure-Fine Insulin Syringe is substantially equivalent to the previous device in terms of indications, compositions, material, design, safety and effectiveness.

Device Name		**Subject Device (Special 510(k))**	**Predicate Device#1 (Existing Traditional 510(k))**
Manufacturer		SHINA MED CORPORATION	SHINA MED CORPORATION
510(k) Number		N/A	K152879
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, 30, 31 Gauge	28, 29, 30,31Gauge
	Length	1/2", 1/4"	1/2", 5/16"
Materials	Needle	STS304	STS304
	Barrel	Polypropylene	Polypropylene
	Plunger	Polypropylene	Polypropylene
	Piston	Isoprene Rubber	Isoprene Rubber
	Needle Cap	Polyethylene	Polyethylene
	Protective end cap	Polyethylene	Polyethylene
	Silicon	Polydimethylsiloxane	Polydimethylsiloxane
Biocompatibility	Conform ISO10993-1	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}	Sterilized by ethylene oxide gas SAL = 10^{-6}

5 Indication for Use :

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

(The indication for use is substantially equivalent to the predicate device.)

6. Technological Characteristics :

Sure-fine insulin syringe and 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 mechanical performance of the needle. To mitigate these risks, appropriate testing was completed to demonstrate that the syringes comply with the following FDA recognized standards:

- ISO7864 - Sterile hypodermic needles for single use - Requirements and test methods
- ISO9626 - Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO8537 - Sterile single-use syringes, with or without needle, for insulin

8. Conclusion

Based on the information provided in this special 510(k), the Sure-fine insulin syringes are substantially equivalent to the previous devices (K152879).