DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 9, 2016

Shina Med Corporation
c/o Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 E. Chapman Ave., Ste. 110
Irvine, California 92831

Re: K152879
Trade/Device Name: Sure-Fine Insulin Syringes
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: August 4, 2016
Received: August 10, 2016

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152879

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

(K152879)

September 07, 2016

1. Submitted by:

Il-hwan, Jeong / Quality Management Representative
SHINA MED CORPORATION
455-30, Bogaewonsam-ro, Bogae-myun, Anseong-si, Gyeonggido, 456-871, Republic of Korea
Phone: +82 31 8057 2125 Fax : + 82 31 8057 2150

2. US Agent/Contact Person:

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110,
Fullerton CA 92831

3. Device Name :

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

4. Predicate Device :

Accu-Sure Insulin syringe (K091167) manufactured by SHINA CORPORATION

5. Device Description:

Sure-Fine Insulin Syringes are designed for the subcutaneous injection of a dose of U-100 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	Plunger 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

This device operates in the principles of a piston syringe. The syringe fluid path is sterile (EO gas sterilization), single use disposable.

6. Indications for Use :

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

7. Technological Characteristics :

The Sure-Fine Insulin Syringes are substantially equivalent to previously marketed device, Accu-Sure Insulin Syringe (K091167) manufactured by Shina Corporation. The device design, materials of construction, manufacturing method, release specifications and performance specifications are the same as the predicate device.

Device Name		Subject Device	Predicate Device
Manufacturer		SHINA MED CORPORATION	SHINA CORPORATION
510(k) Number		K152879	K091167
Product Code		FMF	FMF
Intended Use		Sure-Fine Insulin Syringes are hypodermic insulin syringes for subcutaneous injection of insulin.	Accu-Sure Insulin Syringe is a hypodermic insulin syringe for subcutaneous injection of insulin
Design (Syringe)	Design	Needle / Barrel / Gasket / Plunger / Needle Cap / Protective end cap	Needle / Barrel / Gasket / Plunger / Needle Cap / Protective end cap
	Volume	0.3cc, 0.5cc, 1.0cc	0.3cc, 0.5cc, 1.0cc
	Gauge	28, 29, 30,31Gauge	28, 29, 30,31Gauge
	Length	1/2", 5/16"	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
	Silicone	Polydimethylsiloxane	Polydimethylsiloxane
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. Non-clinical testing

The Sure-Fine Insulin Syringes have been designed and tested to meet the requirements of voluntary standards (listed below) and FDA Guidance documents (Guidance on the Content of Premarket Notification [510(K)] Submissions for Piston Syringes) applicable to the subject and predicate devices. The results of the non-clinical testing supported the conclusion of substantial equivalence.

Performance Testing

The Sure-Fine Insulin Syringes have been designed and successfully tested to meet the applicable requirements outlined in ISO8537.

- Test performed per ISO8537:2007

- ISO 8537-2007 Clause 5 Freedom from extraneous matter
- ISO 8537-2007 Clause 6.Extraction testing
- ISO 8537-2007 Clause 7 Lubrication of syringes and needles
- ISO 8537-2007 Clause 8 Range of sizes
- ISO 8537-2007 Clause 9 Graduated scale
- ISO 8537-2007 Clause 10 Barrel
- ISO 8537-2007 Clause 11 Piston/Plunger assembly
- ISO 8537-2007 Clause 12 Nozzle
- ISO 8537-2007 Clause 13 Needles tubing and needles
- ISO 8537-2007 Clause 14 Performance of assembled syringe

Biocompatibility Testing

The material of the Sure-Fine Insulin Syringes have successfully passed testing as outlined in ISO10993-1 for devices categorized as External communicating devices, Limited exposure.

- ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices Part 10: Test for Irritation and Sensitization 5.4 Intracutaneous reactivity test
- ISO 10993-10 2010 Biological evaluation of medical devices Part 10: Teat for Irritation and Sensitization 6.2 Maximization sensitization test
- ISO 10993-11 2006 Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity 6.5 Acute systemic toxicity
- ISO 10993-4:2002 Biological evaluation of medical devices-Part 4: Selection of tests for interactions with blood.
- The United States Pharmacopeia <151> (Pyrogen test)

Sterilization and Shelf-life Testing

Sterilization of the Sure-Fine Insulin Syringes has been validated using the half-cycle method as outlined in ISO11135.Testing demonstrated maximum levels of residues of ethylene oxide and ethylene chlorohydrins do not exceed the limits presented in IS010993-7. Shelf-life testing supports a shelf-life of 5-years after sterilization.

Clinical Data

No prospective clinical trials were conducted in support of this Traditional 510(k)

9. Discussion

Sure-Fine Insulin Syringes have the same intended use, technological characteristics, materials of construction and performance specifications as the predicate device, Accu-Sure Insulin Syringe (K091167), and thus it performs in a substantial equivalent manner to the predicate device.

10. Conclusion

Based on the information provided in this premarket notification, SHINA MED CORPORATION concludes that the Sure-Fine Insulin Syringes are substantially equivalent to predicate device.