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

Shina Med Corporation
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

June 7, 2016

Re: K152877
Trade/Device Name: SureFine Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: February 29, 2016
Received: March 9, 2016

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. 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,

Susan Runner DDS, MA

Erin I. Keith, M.S.
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)*

K152877

Device Name

SureFine Pen Needle

Indications for Use *(Describe)*

SureFine Pen Needle is intended for use with a pen injector for the subcutaneous injection of 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.

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510(K) SUMMARY
(K152877)

1. Submitted by: June 5, 2016

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2. US Agent/Contact Person:

Priscilla Chung
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2651 E Chapman Ave Ste 110,
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3. Device Name:

- Trade Name : SureFine Pen Needle
- Classification : Class II
- Classification Name : Needle, Hypodermic, Single Lumen
- Product Code : FMI
- Regulation Number : 21 CFR 880.5570
- Review Panel : General Hospital

3. Predicate Device:

ShinaPen® (K113186) manufactured by SHINA CORPORATION

4. Device Description:

The SureFine Pen Needle is designed for use with a pen injector for the subcutaneous injection of insulin. The pen needle consists of a needle, hub, and shield assembly. Blister paper covers primary container. The primary container maintains sterility of the needle because primary container covers the hub and the needle tube with blister paper sealed on the opening hole of primary container.
The needle hub can be connected with the pen**.** The hub has internal threads, which allows it to be screwed onto the pen**.** The needle shield is intended to provide physical protection to the needle tube.
The SureFine Pen Needle is offered in various gauges sizes (29G, 30G, 31G, 32G) and Lengths (4mm, 6mm, 8mm, 12.7mm). These are sterile (Eo gas sterilization) and non-pyrogenic. The pen needles are disposable, single use devices.

5. Intended For Use:

The SureFine Pen Needle is intended for use with a pen injector for the subcutaneous injection of insulin.

6. Technological Characteristics:

The SureFine Pen Needle is substantially equivalent to previously marketed device, ShinaPen® (K113186) manufactured by SHINA CORPORATION. The device design, materials of construction and performance specifications are substantially equivalent to the predicate device.

Device Name		Subject Device	Predicate Device
Manufacturer		SHINA MED CORPORATION	SHINA CORPORATION
510(k) Number		K152877	K113186
Device Name		SureFine Pen Needle	ShinaPen®
Intended for use		The SureFine Pen Needle is intended for use with a pen injector for the subcutaneous injection of insulin.	The ShinaPen® is designed for use with a pen injector for the subcutaneous injection of insulin.
Gauge		29G, 30G, 31G, 32G	29G, 30G, 31G, 32G
Raw Material	Needle tube	STS304	STS304
	Hub	Polypropylene	Polypropylene
	Primary container	Polyethylene	Polyethylene
	Silicone	Poly di-methylsiloxane	Poly di-methylsiloxane
Sterilization		Ethylene oxide gas (SAL 10^{-6})	Ethylene oxide gas (SAL 10^{-6})
Tip configuration (The patient-end of the needle)			
`Tip configuration (The cartridge-end of the needle)			
Needle Sharpness	Min	-27.2g	-27.2g
	Average	-29.20g	-29.20g
	Max	-31.1g	-31.1g
Length		4mm, 6mm, 8mm, 12.7mm	4mm, 6mm, 8mm, 12.7mm
Gauge		29G, 30G, 31G, 32G	29G, 30G, 31G, 32G
Needle shield color		Red / Yellow / Colorless / Blue / Blue / Violet Green Grey	Red / Yellow / Colorless / Blue / Blue / Violet Green Grey
Needle shield dimensions		I.D(2.7mm), O.D(4mm), L(19.35mm)	I.D(2.7mm), O.D(4mm), L(19.35mm)
Needle shield strength	Min	5.8N	5.8N
	Average	8.16N	8.16N

	Max	9.8N	9.8N
Hub/needle bond strength	Min	47.5N	47.5N
	Average	58.02N	58.02N
	Max	61.9N	61.9N

7. Testing

The SureFine Pen Needle has been designed and tested to meet the applicable requirements of voluntary standards and FDA Guidance documents applicable to the subject and predicate devices. The results of the non-clinical testing supported the conclusion of substantial equivalence.

Performance Testing

SureFine Pen Needle has been designed and successfully tested to meet the applicable requirements outlined in ISO 7864:1993, ISO 9626:1991 and ISO 11608-2:2012.

- Tests performed per ISO 7864:1993:
  - ISO 7864:1993 Clause 4 Cleanliness
  - ISO 7864:1993 Clause 5 Limits for acidity or alkalinity
  - ISO 7864:1993 Clause 6 Limits for extractable metals
  - ISO 7864:1993 Clause 7 Size designation
  - ISO 7864:1993 Clause 11.3 Freedom from defects
  - ISO 7864:1993 Clause 11.4 Lubricant
  - ISO 7864:1993 Clause 12 Needle point
  - ISO 7864:1993 Clause 13.1 Bond between hub and needle tube
  - ISO 7864:1993 Clause 13.2 a) Patency of lumen

- Tests performed per ISO 9626:1991 Amd1:2001 (Stainless tubing for SureFine Pen Needle)
  - ISO 9626:1991 Amd1:2001 Clause 3 Materials
  - ISO 9626:1991 Amd1:2001 Clause 4 Surface finish
  - ISO 9626:1991 Amd1:2001 Clause 5 Cleanliness
  - ISO 9626:1991 Amd1:2001 Clause 6 Limits for acidity and alkalinity
  - ISO 9626:1991 Amd1:2001 Clause 7 Size designation
  - ISO 9626:1991 Amd1:2001 Clause 8 Dimensions
  - ISO 9626:1991 Amd1:2001 Clause 9 Stiffness
  - ISO 9626:1991 Amd1:2001 Clause 10 Resistance to breakage
  - ISO 9626:1991 Amd1:2001 Clause 11 Resistance to corrosion

- Tests performed per ISO 11608-2:2012
  - ISO 11608-2:2012 Clause 4.2 Dimensions / Clause 4.2.1 General / Clause 4.2.2 Dimensions for needles
  - ISO 11608-2:2012 Clause 4.3 Determination of flow rate through the needle
  - ISO 11608-2:2012 Clause 4.4 Bond between hub and needle tube
  - ISO 11608-2:2012 Clause 4.5 Needle point
  - ISO 11608-2:2012 Clause 4.6 Freedom from defects
  - ISO 11608-2:2012 Clause 4.7 Lubrication
  - ISO 11608-2:2012 Clause 4.8 Dislocation of measuring point at patient end

- ISO 11608-2:2012 Clause 4.9 Determination of functional compatibility with needle-based injection systems
- ISO 11608-2:2012 Clause 4.10 Ease of assembly and disassembly

And the following insulin injectors are successfully tested and found to be functionally compatible with the following insulin pen-injectors according to ISO 11608-2:2012 section 4.9.
• HUMULIN PEN (3ml) Eli Lilly
• LANTUS SOLOSTAR (3ml) Sanofi Aventis
• FlexPen (3ml) Novo Nordisk

Biocompatibility Testing

The material of the SureFine Pen Needle has successfully passed testing as outlined in ISO 10993-1 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 SureFine Pen Needle 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. LAL testing was performed to demonstrate that bacterial endotoxins are adequately mitigated. Shelf-life testing supports a shelf-life of 3-years after sterilization.

Clinical Data

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

8. Discussion

SureFine Pen Needle has the same intended use, technological characteristics, materials of construction and performance specifications as the predicate K113186 (Shina Pen Needle) and thus it performs in a substantial equivalent manner to the predicate device.

9. Conclusion

Based on the information provided in this premarket notification, SHINA MED CORPORATION concludes that the SureFine Pen Needle is substantially equivalent to predicate device.