April 3, 2025

Shina Med Corporation
% Peter Chung
President
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K250658
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: March 5, 2025
Received: March 5, 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)*
K250658

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.

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:

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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

1. Date of Preparation: March 27, 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
7) Submission date: March 5, 2025
8) Prior related submission : K152877

3. Subject Device Information

1) Trade name : SureFine Pen Needle
2) Common name : Insulin Pen Needle
3) Classification name : Hypodermic single lumen needle
4) Product code : FMI
5) Regulation number : 880.5570
6) Class of device : Class II
7) Panel : General Hospital

4. Predicate Device

1) Trade name (K152877): SureFine Pen Needle
2) Manufacturer: SHINA MED CORPORATION

5. Reference Device

1) Trade name (K210399): Unifine SafeControl
2) Manufacturer: Owen Mumford Ltd

6. Device description

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 needle cap with blister paper sealed on the opening hole of primary container.
The needle hub can be connected screwed onto the pen. The needle shield is intended to provide physical protection to the needle tube.
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), non-toxic, and non-pyrogenic. The pen needles are disposable, single use devices.

7. Indications for Use

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

8. Performance data

1) Bench tests for the device's performance were conducted.

	Test items	Result
ISO 9626	Materials	Pass
	Cleanliness	Pass
	Limits for acidity and alkalinity	Pass
	Size designation	Pass
	Dimension	Pass
	Sitffness	Pass
	Resistance to breakage	Pass
	Resistance to corrosion	Pass

ISO 11608-2	Dimension	Pass
	Flow rate	Pass
	Bond between hub and needle tube	Pass
	Needle point freedom from defects lubrication	Pass
	Dislocation of measuring point at patient	Pass
	Compatibility of needles and injector system	Pass

2) Biocompatibility

Biocompatibility of the Surefine Pen Needle was evaluated in accordance with ISO 10993-1:2018. The following tests were performed: Cytotoxicity; Skin sensitization; Hemocompatibility; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. 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

9. Sterilization and Shelf-life Testing

Sterilization of the SureFine Pen Needle has been validated using the half-cycle method as outlined in ISO 11135. Testing demonstrated maximum levels of residues of ethylene oxide and ethylene chlorohydrins do not exceed the limits presented in ISO 10993-7. LAL testing was performed to demonstrate that bacterial endotoxins are adequately mitigated. Shelf-life testing supports a shelf-life of 5-years after sterilization.

10. Substantially Equivalent (SE) Comparison

	Proposed device	Predicate device	Remark
Manufacturer	SHINA MED CORPORATION	SHINA MED CORPORATION	Same
510(K) No.	K250658	K152877	N/A
Trade Name	SureFine Pen Needle	SureFine Pen Needle	Same
Indications for use	SureFine Pen Needle is intended for use with a pen injector for the subcutaneous injection of insulin.	SureFine Pen Needle is intended for use with a pen injector for the subcutaneous injection of insulin.	Same
Type of use	Prescription use and Over-The-Counter use	Prescription use	Note #1
Components	Primary container Paper seal Needle shield Cannula Needle hub	Primary container Paper seal Needle shield Cannula Needle hub	Same
Needle length	4mm, 6mm, 8mm, 12.7mm	4mm, 6mm, 8mm, 12.7mm	Same
Needle gauge	29G, 30G, 31G, 32G	29G, 30G, 31G, 32G	

Biocompatibility	Conform ISO10993-1 Cytotoxicity Sensitization Irritation Systemic Toxicity Hemocompatibility Pyrogenicity	Conform ISO10993-1 Cytotoxicity Sensitization Irritation Systemic Toxicity Hemocompatibility Pyrogenicity	Same
Needle performance requirements	ISO 11608-2 : 2012 Needle-based injection systems for medical use — Requirements and test methods	ISO 11608-2 : 2012 Needle-based injection systems for medical use — Requirements and test methods	Same
Shelf life	5 years	3 years	Note #2

Note 1 – Type of use
Over-The-Counter use is added to the type of use of for the subject device; however, this change does not alter the indications for use, nor does it affect the safety and effectiveness of the subject device when compared to the predicate device. Thus, the change from Rx only to Rx and OTC does not raise any additional questions of safety or effectiveness when compared to the predicate device.

Note 2 – Shelf-life
The Shelf-life has changed to 5 years from 3 years in comparison with the predicate device. To validate this claim, shelf-life testing for the pen needle was conducted. Therefore, the different shelf-life does not raise new questions of safety or effectiveness compared to the predicate device.

11. Substantially Equivalent (SE) Conclusion

Based on the information provided, the SureFine Pen Needle is substantially equivalent to the predicate device (K152877).