March 18, 2026

Ningbo Medsun Medical Co., Ltd.
Ping Liu
Regulation Affairs Manager
# 298 Huangjipu Rd., Jiangbei,
Ningbo, Zhejiang 315031
China

Re: K253622
Trade/Device Name: Safety Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: February 15, 2026
Received: February 17, 2026

Dear Ping Liu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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)*
K253622

Device Name
Safety Pen Needle

Indications for Use *(Describe)*
The Safety pen needle is intended for use with pen injector devices for subcutaneous injection of drugs. It has sharps protection feature of the patient-end and cartridge-end. For Model SD, the needle tube tip is 3 bevel. For Model SDW, the needle tube tip is 5 bevel.

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

## 1. Date Prepared

March 09, 2026

## 2. Submitter

Ningbo Medsun Medical Co., Ltd.

No. 298 Huangjipu Road, Jiangbei, 315031,Ningbo, P.R.China

Contact Person: Liu Ping, Regulation Affairs Manager

Tel: +86-574-86301887/ Fax:+86-574-86301887

Date Prepared: March 09, 2026

## 3. Device

Trade Name: Safety Pen Needle

Regulation Name: Hypodermic single lumen needle

Regulation Number:21 CFR 880.5570

Regulatory Class: II

Product Code: FMI

Review Panel: General Hospital

## 4. Predicate Device

Manufacturer: Sandstone Medical (Suzhou) Inc.

Device Name: Safety Pen Needle

510(k) Number: K210864

## 5. Device Description

Safety Pen Needle, could be divided into Model SD and Model SDW.

| Model | Mean | Remark |
|---|---|---|
| SD | The patient-end and cartridge-end of the product both have sharps protection feature, the needle tube tip is 3 bevel, the needle tube is thin-wall. | The difference of Model SD and Model SDW only is the needle tip bevel. |
| SDW | The patient-end and cartridge-end of the product both have sharps protection feature, the needle tube tip is 5 bevel, the needle tube is thin-wall. | |

Model SD/SDW consists of needle hub,shield sleeve,rear spring,front spring, slider,

inner shell,protective jacket,needle tube,outer container and seal(dialysis paper).

Safety Pen Needle,could be divided into two models according to the needle tube tip is 3 or 5 bevel; the needle tube is thin-wall. Although the product of different model have different needle tube tip, but the same is that a double-ended needle tube is fixed with needle hub, the needle tip is protected by a protective jacket, the product is sealed with medical dialysis paper and needle container. The device is sterilized by EO gas and for single use. The shelf life is 5 years. The device is non-toxic and non-pyrogenic.

Needle tube is fixed in the center of the needle hub with UV glue, the needle tip is protected with protective jacket before use, medical dialysis paper is covered and sealed needle container to maintain sterile of the device. The cartridge end of needle can be inserted into the rubber of insulin pen, meanwhile the needle hub is connected to insulin pen with screw thread to provide sterile fluid path for injection of insulin during use. The patient end and the cartridge end of the needle tube are lubricated with silicone oil for ease of injection and rubber penetration.

Safety Pen Needle has sharps injury protection feature that it can reduce the occurrence of accidental needlesticks from the patient end and cartridge end of the needle due to the effect of safe-lock guard.

**6. Indications for use**

The Safety pen needle is intended for use with pen injector devices for subcutaneous injection of drugs.It has sharps protection feature of the patient-end and cartridge-end. For Model SD, the needle tube tip is 3 bevel. For Model SDW, the needle tube tip is 5 bevel.

**7. Comparison of Technological Characteristics With the Predicate Device**

| Description | Subject Device (Model SD/Model SDW) (K253622) | Predicate Devices (K210864) | Remark |
|---|---|---|---|
| Proprietary/ trade name | Safety Pen Needle | Safety Pen Needle | / |
| Product Code | FMI | FMI | Same |
| Regulation Number | 21 CFR 880.5570 | 21 CFR 880.5570 | Same |
| Indications for use | The Safety pen needle is intended for use with pen | The safety pen needle is intended for use with pen | Similar (Note 1) |

| | | | |
|---|---|---|---|
| | injector devices for subcutaneous injection of drugs.It has sharps protection feature of the patient-end and cartridge-end. For Model SD, the needle tube tip is 3 bevel.For Model SDW, the needle tube tip is 5 bevel. | injector devices for subcutaneous injection of fluids and FDA-approved drugs.<br>HE Model:<br>Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.<br>HS Model: Additionally, the product has two safety shields, which lock in place after use (patient end) and upon removal of the needle from the pen (pen connection end). The locked shields help reduce the occurrence of needle sticks from both ends of the needle. | |
| Design characteristics | It has sharps protection feature of the patient-end and cartridge-end. | HE Model:<br>The attached safety shield automatically locks in place and reduces the occurrence of accidental needle sticks from the patient end of the needle<br>HS Model:<br>The product has two safety shields, which lock in place after use (patient end) and upon removal of the needle from the pen (pen connection end) | Similar (Note 2) |

| | | | |
|---|---|---|---|
| Prescription/ over-the counter use | Over-the counter use | Over-the counter use | Same |
| Principle of operation for the sharps protection feature | Use the lock shields to help reduce the occurrence of needle sticks | Use the lock shields to help reduce the occurrence of needle sticks | Same |
| Connection method of needle and pen injectors | Twist-on attachment and Twist-off removal | Twist-on attachment and Twist-off removal | Same |
| Operation Mode | Manual | Manual | Same |
| Needle Gauge | 30G,31G,32.5G | 30G,31G,32G,33G | Similar (Note 3) |
| Needle Length | 4mm,5mm,6mm,8mm | 4mm, 5mm, 6mm, 8mm | Same |
| Needle tip | Model SD:3 bevel<br>Model SDW:5 bevel | 3 bevel | Different (Note 4) |
| Wall type | Thin-wall | Thin wall | Same |
| Pen Needle Components | Needle tube,Front spring,Rear spring,Protective jacket,Needle hub, Inner shell, Outer container,Slider,Shield sleeve,Lubricant, Adhesive,Seal | Needle tube,needle hub, needle/hub bond, main body, front shield,big spring,small spring, turning tube,rear shield,safety lock indicator,outer cap, peel tab | Similar (Note 5) |
| Component Materials | Needle tube: Stainless steel;<br>Front spring/Rear spring:Stainless steel<br>Protective jacket: Polypropylene;<br>Needle hub: Polypropylene;<br>Inner shell: Polypropylene;<br>Outer container: Polypropylene;<br>Slider:ABS;<br>Shield sleeve: Polycarbonate; | Needle tube:stainless steel; needle hub:PP;needle/hub bond: adhesive boned;main body:white colored ABS;front shield:transparent ABS or PC;big spring: Carbon steel;small spring: HE model:None,HS model:carbon steel; turning tube:POM; rear shield:red colored ABS; | Similar (Note 6) |

| | | | |
|---|---|---|---|
| | Lubricant:<br>Medical silicone oil;<br>Adhesive:UV glue(A mixture of various acrylic esters and peroxides);<br>Seal:Medical dialyzing paper | safety lock indicator: red band printed on the front shield;<br>outer cap:HDPE;<br>peel tab:medical dialysis paper | |
| Performance | Meet the requirements of ISO 9626, ISO 11608-2,ISO 7864, ISO 23908 | Meet the requirements of ISO 9626, ISO 11608-2,ISO 7864, ISO 23908 | Same |
| Sterilization | EO Sterilization | Gamma irradiation | Different (Note 7) |
| Sterility assurance level (SAL) | $10^{-6}$ | $10^{-6}$ | Same |
| Biocompatibility | Meet the requirements of ISO10993 series standards | Meet the requirements of ISO10993 series standards | Same |

Note 1: The indications for use of the subject device is covered in the predicate device. They are all used for subcutaneous injection of drugs.The subject device has sharps protection feature of the patient-end and cartridge-end for needle sticks. The predicate device(HS Model) also has sharps protection feature of the patient-end and cartridge-end, additionally the predicate device(HE Model) has sharps protection feature of the patient-end for needle sticks. The difference does not raise new questions of safety and effectiveness.

Note 2: The design characteristics of the subject device is covered in the predicate device. The design of subject device has sharps protection feature of the patient-end and cartridge-end for needle sticks. The design of predicate device(HS Model) also has sharps protection feature of the patient-end and cartridge-end, additionally the design of predicate device(HE Model) has sharps protection feature of the patient-end for needle sticks. The difference does not raise new questions of safety and effectiveness.

Note 3: The outer diameter(needle gauge) of the subject device is different from the predicate device. The subject device has 32.5G while the predicate device doesn't have, the predicate device has 32G and 33G while the subject device doesn't have. 32.5G needle tube is between 32G and 33G,which is complies with ISO 9626.On the other hand,

the performance bench testing of needle tube with 32.5G for subject device is demonstrated to meet or refer the requirements of ISO 7864, ISO 9626 and ISO 11608-2.The difference does not raise new questions of safety and effectiveness.

Note 4:The needle tip of the predicate device is 3 bevel, the subject device(Model SD) is 3 bevel and the subject device(Model SDW) is 5 bevel.The 3 bevel and 5 bevel are widely used for Pen Needle in the market and had been approved by FDA. The performance of penetration force and needle points for both 3 bevel and 5 bevel needle tip have been tested and met the requirements of ISO 7864, ISO 9626 and ISO 11608-2. The difference does not raise new questions of safety and effectiveness.

Note 5:The components of the predicate device are mostly the same as the subject device. Just the corresponding names are different.The lubricant is used for subject device, it is not mentioned in the predicate device. The lubricant is widely used for Pen Needle. The safety is demonstrated with the biocompatibility of final product. The differences do not raise new questions of safety and effectiveness.

Note 6:The main materials of the predicate device are mostly the same as the subject device.The materials of the plastic components are commonly used for medical devices, although some plastic materials are different.The materials of the needle tube and needle hub that come into contact with the human body are consistent. The performance bench testing and biocompatibility testing are demonstrated to prove the safety and effectiveness of the subject device when compared to the predicate device.

Note 7: The sterilization method of the predicate device is different with the subject device. The subject device was sterilized by EO, the sterilization process has been validated in accordance with ISO 11135, the EO/ECH residual was tested in the performance bench testing. The above evidence can ensure the safety and effectiveness of the subject device when compared to the predicate device.

**8. Performance Testing Summary**

Performance Test

The performance is according to the following standards and other appropriate standards:

▲ISO 9626 Stainless steel needle tubing for the manufacture of medical devices, and

to performance

▲ ISO 11608-2 Needle-based injection systems for medical use–Requirements and test methods–Part 2: Needles

▲ISO 7864 Sterile hypodermic needles for single use-Requirements and test methods

▲ISO 23908 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features

The test result is as the following table:

| Items | Result |
|---|---|
| Material | Pass |
| Surface finish and visual appearance | Pass |
| Cleanliness | Pass |
| Dimensions | Pass |
| Determination of flow rate through the needle | Pass |
| Bond between hub and needle tube | Pass |
| Needle points | Pass |
| Freedom from defects | Pass |
| Lubrication | Pass |
| Dislocation of measuring point at patient end | Pass |
| Determination of functional compatibility with needle-based injection systems(Dose accuracy and needle removal torque per ISO11608-2) | Pass |
| Ease of assembly and disassembly | Pass |
| Limits for acidity and alkalinity | Pass |
| Stiffness | Pass |
| Resistance to breakage | Pass |
| Resistance to corrosion | Pass |
| Penetration force | Pass |
| Patency of lumen | Pass |

| | |
|---|---|
| Sterility | Pass |
| Bacterial Endotoxin | Pass |
| EO/ECH Residual | Pass |
| Particulate Matter for Injections | Pass |
| Fragmentation Test | Pass |
| Limits for Extractable Metals | Pass |
| Sharps protection feature-<br>Safe-lock guard activation | Pass |
| Sharps protection feature-<br>Safety overriding/unlocking force after activation | Pass |
| Clinical Simulated Use Testing for Sharps Injury Protection | Pass |

Biocompatibility Test

The subject device meets the requirements of ISO 10993 series standards, and the following items are evaluated:In vitro cytotoxicity, skin sensitization, intracutaneous reactivity, acute systemic toxicity, hemocompatibility,subchronic toxicity and pyrogen.The subject device is biocompatible. The following biocompatibility data is provided in support of the substantial equivalence.

| Items | Requirements | Result |
|---|---|---|
| Hemocompatibility | ASTM F756-17<br>ISO 10993-4:2017/Amd.1:2025 | Pass |
| In vitro cytotoxicity | ISO 10993-5: 2009 | Pass |
| Skin sensitization | ISO 10993-10: 2021 | Pass |
| Intracutaneous reactivity | ISO 10993-23:2021/Amd 1:2025 | Pass |
| Acute Systemic toxicity | ISO 10993-11:2017 | Pass |
| Pyrogen | ISO 10993-11: 2017<br>USP <151> | Pass |
| Subchronic Toxicity | ISO 10993-11:2017 | Pass |

The compatible pen injectors are verified in Functional Compatibility with Needle-based Injection Systems, the following compatible pen injectors of commonly used in the U.S. market are compatible with the device to use.

| No. | Specification | 510(k) No. | Manufacturer |
|---|---|---|---|
| 1 | NovoPen Echo | K162602 | Novo Nordisk Inc. |
| 2 | Humapen Luxura | K142518 | Eli Lilly and Company |
| 3 | Humapen Luxura HD | K100988 | Eli Lilly and Company |

| | | | |
|---|---|---|---|
| 4 | HumanPen Ergo II | K151686 | Eli Lilly and Company |

## 9. Conclusions

Based on device comparison information and non-clinical bench testing, the subject device is substantially equivalent to the predicate device.