March 25, 2026

Sandstone Medical (Suzhou) Inc.
Susan Sun
Quality Manager
No.168 PuTuoShan Road, New District
Suzhou, Jiangsu 215253, China

Re: K252908
Trade/Device Name: Easydrip Classic Pen Needle; Easydrip Plus Pen Needle; Easydrip Classic Pro Pen Needle; Easydrip Plus Pro Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: August 27, 2025
Received: February 23, 2026

Dear Susan Sun:

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)*
K252908

Device Name
Easydrip Classic Pen Needle; Easydrip Plus Pen Needle; Easydrip Classic Pro Pen Needle; Easydrip Plus Pro Pen Needle

Indications for Use *(Describe)*
The pen needle is intended for use with pen injector devices for subcutaneous injection of fluids and FDA-approved drugs.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025/08/27

1. Submission sponsor

Name: Sandstone Medical (Suzhou) Inc.
Address: Building 6, No.168 PuTuoShan Road, New District, 215153 Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA
Contact person: Susan Sun
Title: Quality Department Manager
E-mail: registration@sandstonemed.com
Tel: 86-13812630746

2. Subject Device Information

Trade/Device Name	Easydrip Classic Pen Needle; Easydrip Plus Pen Needle; Easydrip Classic Pro Pen Needle; Easydrip Plus Pro Pen Needle
Model	Classic, Plus, Classic Pro, Plus Pro
Common Name	Pen Needles
Regulatory Class	Class II
Classification	21CFR 880.5570 / Needle, Hypodermic, Single Lumen / FMI
Submission type	Special 510(K)

3. Predicate Device

Sandstone Medical (Suzhou) Inc., Easydrip Pen Needle; Easydrip Plus Pen Needle, under K193422.

4. Device Description

Easydrip Pen Needles are single-use, sterile, and non-pyrogenic medical device designed to be used with pen injector devices for subcutaneous injection of fluids and FDA-approved drugs. The subject devices include four models, i.e. Easydrip Classic, Easydrip Classic Pro, Easydrip Plus, and Easydrip Plus Pro. All models have the same operation methods and similar materials. The device comprises a stainless needle, needle hub, inner cap, outer cap and sealing paper, and the needle surface coated with silicone oil. The needle hub of the device can be screwed onto compatible pen injector devices.

5. Intended use & Indication for use

The pen needle is intended for use with pen injector devices for subcutaneous injection of fluids and FDA-approved drugs.

6. Comparison to the Predicate Device

The comparison and discussion between the subject device and the predicate devices are listed in below：

Table1-General Comparison of Pen Needle

Item	Predicate Device（K193422）	Proposed Device	Comparison/Statement
Product name	Easydrip Pen Needle; Easydrip Plus Pen Needle	Easydrip Classic Pen Needle; Easydrip Plus Pen Needle; Easydrip Classic Pro Pen Needle; Easydrip Plus Pro Pen Needle	Two new models, Easydrip Classic Pro and Easydrip Plus Pro, have been added. Performance testing carried out on the new models shows that there are no new or different questions of safety and effectiveness.
Manufacturer	Sandstone Medical (Suzhou) Inc.	Sandstone Medical (Suzhou) Inc.	No change
Product Code	FMI	FMI	No change
Regulation Number	21 CFR 880.5570	21 CFR 880.5570	No change
Classification	II	II	No change
Type of use	Single Use	Single Use	No change
Intended use/ Indications for use	The Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.	The pen needle is intended for use with pen injector devices for subcutaneous injection of fluids and FDA-approved drugs.	Different. Change from specific use (insulin) to general use (drugs). The broader intended use/ indication for use does not introduce new questions of safety or effectiveness when compared to the predicate device as the device's mechanism remains unchanged.
Operation mode	Manual	Manual	No change
Sterilization method and SAL	SAL: 10^{-6} Method: Irradiation Sterilized	SAL: 10^{-6} Method: Irradiation Sterilized	No change

Component and Material	**Needle tube:** 304 Stainless steel Needle base: Polypropylene **Inner cap:** Polyethylene/ polypropylene **Outer cap:** Polyethylene **Sealing paper:** Sealing dialysis paper	**Needle tube:** 304 Stainless steel **Needle hub:** Polypropylene **Inner cap:** Polyethylene or polypropylene **Outer cap:** Polyethylene or polypropylene **Sealing paper:** Sealing dialysis paper		Different. The outer cap of the subject device is different from that of the predicate. However, the difference in material is addressed through biocompatibility testing. The biocompatibility testing reports demonstrates that the difference in material does not raise new or different questions of the safety and effectiveness when compared to the predicate device.
Needle gauge	29G/30G/31G/32G/33G	29G/30G/31G/32G/33G		29 G models is removed for the Easydrip Plus and Easydrip Plus Pro models. Removal of this specification does not raise new or different questions of safety and effectiveness when compared to the predicate device.
Needle Length	4mm, 5mm, 6mm, 8mm, 10mm, 12mm, 12.7mm	4mm, 5mm, 6mm, 8mm, 10mm, 12mm, 12.7mm		No change
Bevel	Bevel	Bevel	Model	Different. 5-bevel needle was added. The introduction of a 5-bevel needle design is intended to enhance user experience. Performance testing on the new models shows that addition of the 5-bevel needle tip does not raise new or different questions of safety and effectiveness when compared to the predicate device.
	3	3	Classic; Plus	
		5	Classic Pro; Plus Pro	
Performance requirements	Complied with ISO 9626 and ISO 11608-2	Complied with ISO 9626 and ISO 11608-2		No change
Shelf Life	5 years	5 years		No change
Biocompatibility	Complied with ISO10993 series standards	Complied with ISO10993 series standards		No change
Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801		Different. Differences in labeling are due to changes noted above. Labeling complies with 21CFRPart 801 and does not raise new or different

			questions of safety and effectiveness as compared to the predicate.

The following changes were identified between the subject and predicate devices:

1) Indications for Use: The broadened indications for use in the subject device from the predicate device does not raise new or different questions of safety and effectiveness as the device's principle of operation remains the same.
2) Introduction of Plus Pro and Classic Pro Models (5-bevel needle): The addition of new models (5-needle bevel) expands options. Additionally, the new 5-bevel needle met the internal quality standards of enterprises, and the performance testing result meet the requirements and shows that the addition of the new bevel does not raise new or different questions of safety and effectiveness when compared to the predicate device .
3) Material: The outer cap material for the subject devices (Classic Pro and Plus Pro) has been changed from exclusively polyethylene (PE) to also allow for the use of polypropylene (PP). Biocompatibility testing per ISO 10993 on this skin-contacting component confirms that the change does not raise new or different questions of safety and effectiveness when compared to the predicate device.
4) Removal of the 29G needles for the Plus and the Plus Pro models: This narrowing of the product specification scope does not involve changes to device design, materials, manufacturing processes, sterilization methods, or operating principles and, therefore, does not raise new or different questions of safety and effectiveness as compared to the predicate.

7. Non-clinical Testing

All non-clinical testing performed on the subject devices is to demonstrate substantial equivalence to the predicate device. Tests setup and execution are performed in accordance with applicable standards.
The following performance data was provided to support a substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the proposed device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Intracutaneous reactivity
- Acute systemic toxicity
- Hemocompatibility
- Pyrogen

Non-clinical data

The bench testing performed verifies that the performance of the subject devices are substantially equivalent in terms of critical performance characteristics to the predicate device. These tests include:

- Surface finish and visual appearance, needle points, freedom from defects.
- Needle tubing dimensions

- Stiffness and resistance to breakage of needle tubing
- Dimensions for double-ended pen needle assembly
- Flow rate passing through the needle
- Bond between hub and needle tube
- Dislocation of measuring point at patient end
- Ease of assembly
- Needle removal torque
- Compatibility of needle and injection system
- Particulate Tests

8. Conclusion

Differences in the technological characteristics of the subject device when compared to the predicate devices have been successfully evaluated through performance testing and biocompatibility testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of safety and effectiveness. Therefore, the Pen Needles have been determined to be substantially equivalent to the predicate device.