February 17, 2022

Sandstone Medical (Suzhou) Inc.
% Grace Liu
Consultant
Shenzhen Joyantech Consulting Co., Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K210864
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: January 11, 2022
Received: January 18, 2022

Dear Grace 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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

CAPT Alan Stevens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210864

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 fluids and FDA-approved drugs.

HE Model
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.

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.

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.

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510(k) Summary

1. Contact Details

Applicant Name	Sandstone Medical (Suzhou) Inc.
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Date Prepared	2022-01-11
Website	www.sandstonemed.com

2. Device information

Trade name	Safety Pen Needle
Common name	Safety Pen Needle
Classification	Class II
Classification name	Needle, Hypodermic, Single Lumen
Product code	FMI
Regulation No.	880.5570

3. Legally Marketed Predicate Device

Trade Name	Clickfine AutoProtect Pen Needle
510(k) Number	K152514
Product Code	FMI
Manufacturer	Ypsomed AG

4. Device Description

The proposed device, Safety Pen Needle, is a sterile, non-pyrogenic, single-use device, which is intended for use with pen injector devices for subcutaneous injection of fluids and FDA-approved drugs. It incorporates a sharps injury prevention feature, which can reduce the occurrence of accidental needle sticks.

The proposed device is provided with two models, i.e. HE Model and HS Model. HE Model has an attached safety shield, which can automatically lock in place and reduce 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. HS Model 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 accidental needle sticks from both ends of the needle.

Both of HE Model and HS Model contain main body, needle hub, needle tube, front shield, rear shield, big spring, turning tube, container (outer cap) and peel tab (sealing paper). Both ends of the needle

tube (i.e. the patient end and the pen connection end) is lubricated by silicone oil. The needle tube and the needle hub are bonded by glue. The container sealed with the peel tab constitutes the sterile barrier system. The common components of both models are almost the same in materials and structure and size, and the only difference is the structure of the rear shield. The biggest difference between the two models is that HS Model contains a small spring additionally and has a relatively more complex structure.

The specifications for each model are designated by the gauge of needle tube and needle available length. Both models have the same specifications (shown in the following table).

Specification	Needle Tube			
	Gauge (G)	Designated metric size (mm)	Outer Diameter (mm)	Needle Available Length (mm)
30G×3/16” 0.30mm×5mm	30	0.30	0.298-0.320	5
30G×5/16” 0.30mm×8mm				8
31G×3/16” 0.25mm×5mm	31	0.25	0.254-0.267	5
31G×1/4” 0.25mm×6mm				6
31G×5/16” 0.25mm×8mm				8
32G×5/32” 0.23mm×4mm	32	0.23	0.229-0.241	4
32G×3/16” 0.23mm×5mm				5
32G×1/4” 0.23mm×6mm				6
33G×5/32” 0.20mm×4mm	33	0.20	0.203-0.216	4
33G×3/16” 0.20mm×5mm				5

Safety Pen Needle is used by peeling back the peel tab and screwing the needle hub onto the threaded end of the pen injector. The pen connection end of the needle tube punctures the septum of the cartridge in the pen injector. The outer protective container is then removed. When the injection is needed, the needle is vertically inserted into the chosen site. While inserting the needle into the skin, the front shield moves backward into the main body enabling the needle to penetrate the skin and the subcutaneous tissue, and the safety mechanism is activated. Then, the pen injector delivers the medicinal product through the needle.

After the injection, Safety Pen Needle is withdrawn from the skin. The big spring pushes the front shield to move forward until the front shield reaches its limit position where the red band indicator on the front shield appears outside the main body and can be seen. At this time, the front shield completely covers the needle tip at the patient end and is locked in place, and Safety Pen Needle enters the patient-end protection state and it can no longer be used.

Additionally, for HS Model, when Safety Pen Needle is screwed off, the small spring pushes the rear shield to move towards the pen connection end until the rear shield reaches its limit position. At this time, the rear shield completely covers the needle tip at the pen connection end and is locked, and Safety Pen Needle enters the pen-connection-end protection state.

The proposed device is sterilized by Gamma irradiation to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

5. Intended Use/Indication for Use

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

HE Model
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.

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.

6. Substantial Equivalence Comparison

Item	Proposed Device: Safety Pen Needle (HE Model and HS Model) (K210864)	Predicate Device: Clickfine AutoProtect Pen Needle (K152514)	Comments
Product Code	FMI	FMI	Same
Intended use	The safety pen needle is intended for use with pen injector devices for subcutaneous injection of fluids and FDA-approved drugs. For HE Model 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. For 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.	The Clickfine AutoProtect Pen Needle is intended for use with pen injector devices for the injection of fluids, including insulin and exenatide. 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.	Similar (Issue 1)
OTC use	Yes	Yes	Same
Single use	Yes	Yes	Same
Operation mode	Manual	Manual	Same
Operating principle	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
Needle gauge	30G, 31G, 32G, 33G	29G, 30G, 31G	Different (Issue 2)
Needle length	4mm, 5mm, 6mm, 8mm	5mm, 6mm, 8mm	
Needle wall thickness	Thin wall	Regular wall, Thin wall	Similar
Needle grind	Front and back bevel	Front and back bevel	Same
Tip geometry	3 bevel	3 bevel	Same

Item		Proposed Device: Safety Pen Needle (HE Model and HS Model) (K210864)	Predicate Device: Clickfine AutoProtect Pen Needle (K152514)	Comments
Method of attachment to pen		“Twist-on” attachment and Twist-off removal	"Snap-on" & “Twist-on” attachment and Twist-off removal	Different (Issue 3)
Sterilization		SAL: 10^{-6}	SAL: 10^{-6}	Same
		Method: Gamma irradiation	Method: Gamma irradiation	Same
Visual indicator		Red band	Red band	Same
Configuration and Material	Needle tube	Stainless steel	Stainless steel	Same
	Need hub	PP	PP	Same
	Needle/hub bond	Adhesive bonded	Adhesive bonded	Same
	Main body	White colored ABS	White colored PP	Different (Issue 4)
	Front shield	Transparent ABS or PC	Blue colored MBS, using the Zylar 530 granulate	
	Big spring	Carbon steel	Stainless steel	
	Small spring	HE Model: None HS Model: Carbon steel	None	
	Turning tube	POM	Unknown	
	Rear shield	Red colored ABS	None	
	Safety lock indicator	Red band printed on the front shield	Red colored PP	
	Outer cap	HDPE	Blue colored PP	
	Peel tab	Medical dialysis paper	PET	
Performance		Complied with ISO 11608-2, ISO 7864, ISO 9626 and ISO 23908.	Complied with ISO 11608-2, ISO 7864, ISO 9626 and ISO 23908.	Same
Biocompatibility		Complied with ISO 10993-1, USP <788> Method 1	Complied with ISO10993-1	Same

Issue 1:
Both of the proposed devices and the predicate device are intended for subcutaneous injection.

HS Model of the proposed device incorporates an additional safety shield compared with the predicated device such that HS Model has two safety shields lock in place: (I) after use (patient end) and (II) upon removal of the needle from the pen (pen connector end). The lock shields help reduce the occurrence of needle sticks from both ends of the needle. This additional protection does not constitute a new intended use. However, the indication for use describes this additional safety shield. Both of the proposed devices and the predicate device help protect against accidental needle sticks.

Issue 2:
Compared with the predicate device, the proposed device has two additional needle gauges of 32G and 33G and two additional needle lengths of 4mm and 5mm. The difference in needle gauge and length does not impact safety or performance and raises no new questions of safety and performance. The subject device and predicate are both intended for subcutaneous injection. In this case, the difference is still intended for subcutaneous tissue, which is the same tissue as the predicate. The additional needle gauge and length are being introduced to meet individual needs of patients based on their skin type, BMI, and drug dosing and treatments.

Issue 3:
The predicate device is snapped firstly and then screwed onto the threaded end of the pen injector, while the proposed device is screwed onto the threaded end of the pen injector. Eventually, both devices are secured on the pen injector by the fit between threads. Moreover, the performance testing of the proposed device has demonstrated that the “Twist-on” attachment can meet the requirements in the compatibility with needle-based injection system test. Therefore, the difference on the method of attachment to pen doesn’t affect the substantial equivalence.

Issue 4:
The difference on the configuration between the proposed device and the predicate device mainly results from the different safety mechanisms. The differences do not raise new questions of safety and effectiveness.

7. Non-clinical Testing

All non-clinical testing performed on the proposed device is to demonstrate the substantial equivalence to the predicate device. Tests are performed in accordance with the applicable standards. Results of the testing demonstrate the compliance with the standards.

- The following performance data is provided in support of the substantial equivalence determination.

Test	Requirements	Results
Materials	Clause 4.1 of ISO 11608-2	Pass
Tubing dimensions	Clause 4.2.1 of ISO 11608-2 and Clause 5.6 of ISO 9626	Pass
Dimensions for needles	Clause 4.2.2 of ISO 11608-2	Pass
Flow rate through needle	Clause 4.3 of ISO 11608-2	Pass
Bond between hub and needle tube	Clause 4.4 of ISO 11608-2 and Clause 4.12 of ISO 7864	Pass
Needle points	Clause 4.5 of ISO 11608-2	Pass
Freedom from defects	Clause 4.6 of ISO11608-2	Pass
Lubrication	Clause 4.7 of ISO 11608-2	Pass
Dislocation of measuring point at patient end	Clause 4.8 of ISO 11608-2	Pass
Compatibility with needle-based injection system and Ease of assembly and disassembly	Clause 11 of ISO 11608-2	Pass
Stiffness of needle tubing	Clause 5.8 of ISO 9626	Pass
Resistance to breakage of needle tubing	Clause 5.9 of ISO 9626	Pass
Activation of the sharps injury protection feature	Clause 4.2 of ISO 23908	Pass
Challenging the device in safe mode	Clause 4.3 of ISO 23908	Pass

- The following biocompatibility data is provided in support of the substantial equivalence determination.

Test	Requirements	Results
In vitro Cytotoxicity	ISO 10093-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Pass
Skin Sensitization	ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Pass
Intracutaneous Reactivity	ISO 10993-10 Biological evaluation of medical devices – Part 10:Tests for irritation and skin sensitization	Pass
Acute Systemic Toxicity	ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	Pass
Haemocompatibility	ASTM F756 Standard Practice for Assessment of Hemolytic Properties of Materials	Pass
Pyrogen	ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity USP 42-NF37 <151> Pyrogen Test	Pass
Bacterial Endotoxins	USP42_NF37 <85> Bacterial Endotoxins Test	Pass
Particulates	USP <788>, Method 1 Light Obscuration Test	Pass

- Simulated clinical use study

Simulated clinical use study was conducted to verify the safety feature per *Guidance for Industry and FDA Staff - Medical Devices with Sharps Injury Prevention Features, issued on August 9, 2005*. 500 subject devices were evaluated by both professional healthcare users and non-clinical pen users in the simulated clinical use study. There was no needlestick injuries occurred and zero failure of the protective feature in the study.

- Sterilization

A Sterility Assurance Level (SAL) of 10^{-6} has been validated in accordance with the requirements of ISO 11137 series standards.

- Packaging and shelf life

Accelerated packaging testing was performed to assure a 5 year shelf life.

8. Clinical Testing

Substantial equivalence does not depend on the clinical test data.

9. Conclusions

Based on device comparison information and non-clinical bench testing, the proposed device is substantially equivalent to legally marketed predicate device (K152514).