February 2, 2021

Sandstone Medical (Suzhou) Inc.
% Elly Xu
Consultant Manager
Shenzhen Joyantech Consulting Co., Ltd
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, 518000 Cn

Re: K193422
Trade/Device Name: Easydrip Pen Needle, Easydrip Plus Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: November 27, 2020
Received: December 28, 2020

Dear Elly Xu:

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,

For Rumi Young
Acting 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)*
K193422

Device Name
Easydrip Pen Needle, Easydrip Plus Pen Needle

Indications for Use *(Describe)*
The Pen Needle is intended for use with pen injector device for 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.

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510(k) Summary

510(k) Number: K193422

1. Contact Details

1.1 Applicant information

Applicant Name	Sandstone Medical (Suzhou) Inc.
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Date Prepared	November 29, 2019
Website	www.sandstone.com

1.2 Consultant information

Name	Shenzhen Joyantech Consulting Co., Ltd
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Contact person	Joyce Yang, Field Fu
Contact person's e-mail	joyce@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Easydrip Pen Needle, Easydrip Plus Pen Needle
Common name	Insulin Pen Needle
Model	29G/30G/31G/32G/33G
Classification	Ⅱ
Classification name	Needle, Hypodermic, Single Lumen
Product code	FMI
Regulation No.	21 CFR 880.5570

3. Legally Marketed Predicate Device

Trade Name	Verifine® Common Type Insulin Pen Needle
510(k) Number	K161950
Product Code	FMI
Manufacturer	Promisemed Hangzhou Meditech Co., Ltd.

4. Device Description

The proposed devices, Pen Needles, are a single-use device, which is designed for use with a pen injector for the subcutaneous injection of insulin. The proposed devices include two models, i.e. Easydrip Pen Needle and Easydrip Plus Pen Needle. Both models have the same construction, operation methods and similar materials. Both models consist of needle tubing, needle tip shield, needle base, needle container, sealing dialysis paper, glue and silicone oil. The needle base of the device can be screwed onto compatible insulin pens. The only minor differences between the Easydrip and Easydrip Plus models are the outer shape and the material of the Needle tip shield. The Easydrip Needle tip shield is slightly shorter in length and more tapered than the Easydrip Plus Needle tip shield. The material of construction of the Easydrip Needle tip shield is polyethylene, while the Easydrip Plus Needle tip shield is polypropylene.

The Pen Needles are offered in various gauge sizes and needle lengths. The proposed devices are irradiation sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

The dimension for both Easydrip Pen Needle and Easydrip Plus Pen Needle are shown as below.

Type	Gauge(G)	Needle OD.(mm)	Needle available length(mm)
Easydrip	29	0.33	10
			12
			12.7
	30	0.30	6
			8
			10
	31	0.25	5
			6
			8
	32	0.23	4
			5
	33	0.20	4
			5
Easydrip Plus	29	0.33	10
			12
			12.7
	30	0.30	6
			8
			10
	31	0.25	5
			6
			8
	32	0.23	4
			5
	33	0.20	4
			5

5. Intended Use/Indication for Use

The Pen Needle is intended for use with pen injector device for subcutaneous injection of insulin.

6. Product compatibility

The Pen Needle may be used with Type A compatible insulin delivery system, including:

Pen name	**Pen Manufacturer**
NovoPen 5	Novo Nordisk
AUTOPEN 24	Owen mumford
Gansulin Pen	Tonghua Dongbao
Ypsopen	Ypsomed AG
UNIPEN	United Laboratories
XiuLin Pen	Gan & Lee
HumaPen Ergoll	ElLILILLY
Byetta	Baxter Pharmaceutical
Victoza Pen	Novo nordisk

7. Substantial Equivalence Comparison

Item	**Proposed Device:** Easydrip Pen Needle	**Proposed Device:** Easydrip Plus Pen Needle	**Predicate Device:** Common Type Insulin Pen Needle (K161950)	**Comments**
Product Code	FMI	FMI	FMI	Same
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 device for subcutaneous injection of insulin.	The Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.	Same
Configuration and Material	Needle tubing (Needle Tube):304 Stainless steel	Needle tubing (Needle Tube):304 Stainless steel	Needle tubing (Needle Tube):304 Stainless steel,	Same
	Needle tip shield (Tube Sheath): Polyethylene	Needle tip shield (Tube Sheath): Polypropylene	Needle tip shield (Tube Sheath): Polypropylene	Difference #1
	Needle base (Hub): Polypropylene	Needle base (Hub): Polypropylene	Needle hub: Polypropylene	Same
	Needle container (Hub Sheath): Polyethylene	Needle container (Hub Sheath): Polyethylene	Needle container (Hub Sheath): Polyethylene	Same

Item	**Proposed Device:** Easydrip Pen Needle	**Proposed Device:** Easydrip Plus Pen Needle	**Predicate Device:** Common Type Insulin Pen Needle (K161950)	**Comments**
	Sealing dialysis paper (Sealed Paper): Sealing dialysis paper	Sealing dialysis paper (Sealed Paper): Sealing dialysis paper	Sealing dialysis paper (Sealed Paper): Sealing dialysis paper	Same
Operation mode	Manual	Manual	Manual	Same
Needle Gauge	29G/30G/31G/32G/33G	29G/30G/31G/32G/33G	29G/30G/31G/32G/33G	Same
Needle length	4mm, 5mm, 6mm, 8mm, 10mm,12mm, 12.7mm	4mm, 5mm, 6mm, 8mm, 10mm,12mm, 12.7mm	4mm, 5mm, 6mm, 8mm,12mm	Difference #2
Design of the needle base				Same
Sterilization	SAL: 10^{-6}	SAL: 10^{-6}	SAL: 10^{-6}	Same
	Method: Irradiation Sterilized	Method: Irradiation Sterilized	Method: EO Sterilized	Difference #3
Performance	Complied with ISO 7864, ISO 9626, and ISO 11608-2	Complied with ISO 7864, ISO 9626, and ISO 11608-2	Complied with ISO 7864, ISO 9626, and ISO 11608-2	Same
Shelf Life	5 years	5 years	5 years	Same
Single Use	Yes	Yes	Yes	Same
Biocompatibility	Complied with ISO 10993 series standards	Complied with ISO 10993 series standards	Complied with ISO 10993 series standards	Same
Cytotoxicity	No cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Skin Irritation	No evidence of skin irritation	No evidence of skin irritation	No evidence of skin irritation	Same
Skin Sensitization	No evidence of sensitization	No evidence of sensitization	No evidence of sensitization	Same
Acute Systemic Toxicity	No systemic toxicity	No systemic toxicity	No systemic toxicity	Same
Hemolysis	No evidence of hemolysis	No evidence of hemolysis	No evidence of hemolysis	Same
Pyrogen	No pyrogen	No pyrogen	No pyrogen	Same

8. Substantial Equivalence Discussion

Difference #1 – Needle tip shield material

The needle tip shield of the Easydrip Pen Needle is different from that of the predicate. However, the difference in material is addressed through biocompatibility testing according to ISO 10993 series standards. The biocompatibility testing demonstrates that the difference in material does not affect the safety and effectiveness of the device.

Difference #2 - Needle length

Compared to the predicate device, the proposed device has an additional 12.7mm needle length. The bench tests of the needle with 12.7mm needle length demonstrated conformance to ISO 7864, ISO 9626, and ISO 11608-2. Therefore, the additional needle length does not affect the safety and effectiveness of the device.

Difference #3 - Sterilization method

The subject device is irradiation sterilized while the predicate device is Ethylene Oxide sterilized. While the sterilization methods between the proposed device and the predicate device are different, validation testing was performed to validate the sterilization method. The sterilization report showed that the sterilization effect of the proposed device can achieve a Sterility Assurance Level (SAL) of 10^{-6}, and the radiation dose audit test reports showed that the minimum gamma radiation dose to achieve a 10^{-6} SAL was acceptable according to ISO 11737-2:2012. Therefore, the difference in sterilization does not affect the safety and effectiveness of the device.

9. 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.

Test	Requirements	Results
Materials	The needle shall be made of tubing materials specified in ISO 9626.	Passed
Dimensions	The needles shall fit the test apparatus specified in item 7.2 of ISO 11608-2.	Passed
Flow rate through the needle	The needles were tested in accordance with Annex A to ISO 11608-2.	Passed
Binding force between needle base and needle tubing	The union of the hub and needle tube shall not break when tested in accordance with Clause 9 of ISO 11608-2.	Passed

Test		Requirements	Results
Needle tip appearance, needle tubing flawlessness, size of inside and outside diameter and puncturing force		The needle tip appearance shall fulfil the 4.5 of ISO 11608-2. The needle tubing flawlessness shall fulfil the requirements of ISO 7864:1993, 11.3.	Passed
Dislocation of measuring point patient end		Dislocation of the cannula point at the patient end shall be in accordance with Table 2 (ISO 11688-2) when tested in accordance with Clause 8 of ISO 11608-2.	Passed
Functional compatibility with needle-based injected systems		Compatibility with any NIS shall be claimed only after testing in accordance with Clause 11 of ISO 11608-2.	Passed
Ease of assemble and disassembly		Attachment of the needle shall be possible without removing the needle from its opened unit packaging. Compliance is checked according to the requirements of Clause 11 of ISO 11608-2.	Passed
Biocompatibility	Cytotoxicity	ISO 10093-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity	Passed
	Sensitization	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization	Passed
	Irritation	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization	Passed
	Hemocompatibility	ISO 10993-4 Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood ASTM F765 Standard Practice for Assessment of Hemolytic Properties of Materials	Passed
	System toxicity (acute)	ISO 10993-11:2006/(R)2010, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.	Passed
	Pyrogen	USP 40.NF 35 <151> Pyrogen Test.	Passed
	Particulate Matter	USP <788> Particulate Matter in Injections, Method 1: Light Obscuration Particle Count Test	Passed

10. Clinical Testing

No clinical test data was included in this submission.

11. Conclusions

Based on device comparison information and non-clinical bench testing, the Pen Needle and the predicate device have the same indication for use, similar materials of construction, and similar specifications. The bench tests and biocompatibility tests support that the proposed device is as safe and effective as the predicate device, and the differences between them do not raise any new

questions of safety and effectiveness. Therefore, the proposed device is determined to be

Substantially Equivalent to legally marketed predicate device.