DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 29, 2016

SteriLance Medical (Suzhou) Inc.
c/o Mr. Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
No. 55 Shizhou Middle Road
Nanshan District, Shenzhen, GD755
CHINA

Re: K153706
Trade/Device Name: Easy Drip Disposable Insulin Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: July 15, 2016
Received: July 28, 2016

Dear Mr. Fu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153706

Device Name
Easy Drip Disposable Insulin Needle

Indications for Use *(Describe)*
The Insulin 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.

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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"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

K153706

1. Contact Details

1.1 Applicant information

Applicant Name	SteriLance Medical (Suzhou) Inc.
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1.2 Submission Correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
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Contact person	Field Fu
Contact person's e-mail	cefda13485@163.com; elly@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	Easy Drip Disposable Insulin Needle
Common name	Insulin Pen Needle
Model	29G/30G/31G/32G
Classification	II
Classification name	Needle, Hypodermic, Single Lumen
Product code	FMI
Regulation No.	880.5570

3. Legally Marketed Predicate Device

Trade Name	Insulin Pen Needle
510(k) Number	K133059
Product Code	FMI
Manufacturer	Wenzhou Beipu Science & Technology Co., Ltd

4. Device Description

The proposed device, Pen Needle, is a single-use device, which is designed for use with a pen injector for the subcutaneous injection of insulin. It consists of needle tubing, needle tip shield, needle base, needle base shield, sealing dialysis paper, glue and silicone oil. The needle base can be connected screwed onto the insulin pen.

The Pen Needle is offered in various gauge size and length.

The proposed device is available in radiation sterilized to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

5. Intended Use/Indication for Use

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

6. Substantial Equivalence Comparison

Item	Proposed Device: Insulin Pen Needle	Predicate Device: Insulin Pen Needle (K133059)	Comments
Product Code	FMI	FMI	Same
Intended Use	The Insulin 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	Needle tubing (Needle Tube), Needle tip shield (Tube Sheath), Needle base (Hub), Needle base shield (Hub Sheath), Sealing dialysis paper (Sealed Paper).	Needle Tube, Hub, Tube Sheath, Hub Sheath and Sealed Paper.	Same
Operation mode	Manual	Manual	Same
Needle Gauge	29G/30G/31G/32G	29G/30G/31G/32G	Same
Material	Tube: 304 Stainless Steel	Tube: 304 Stainless Steel	Same
	Needle base: Polyformaldehyde	Hub: Polypropylene	Similar (*1)
Sterilization	SAL: 10^{-6}	SAL: 10^{-6}	Same
	Method: Radiation Sterilized	Method: EO Sterilized	Different (*2)
Performance	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	Same
Single Use	Yes	Yes	Same
Biocompatibility	Complied with ISO10993 series standards	Complied with ISO10993 series standards	Same
Cytotoxicity	Under the conditions of the	Under the conditions of the	Same

	study, the subject device showed no evidence of cytotoxicity	study, the subject device showed no evidence of cytotoxicity	
Skin Irritation	Under the conditions of the study, the subject device showed no evidence of skin irritation	Under the conditions of the study, the subject device showed no evidence of skin irritation	Same
Skin Sensitization	Under the conditions of the study, the subject device showed no evidence of sensitization	Under the conditions of the study, the subject device showed no evidence of sensitization	Same
Acute Systemic Toxicity	Under the conditions of the study, the subject device showed no evidence of systemic toxicity	Under the conditions of the study, the subject device showed no evidence of systemic toxicity	Same
Hemolysis	Under the conditions of the study, the subject device showed no evidence of hemolysis	Under the conditions of the study, the subject device showed no evidence of hemolysis	Same
Pyrogen	non-pyrogenic	non-pyrogenic	Same

***1:** The needle base materials are different, but Polyformaldehyde and Polypropylene are all the common plastic materials. The biocompatibility and performance testing reports of the proposed device demonstrate that subject device is biocompatible and the performance as intended.

***2:** The sterilization methods between the proposed device and the predicate device are different. The radiation sterilization method for the proposed device is proved by the *Microbiological Validation Report of Gamma Radiation Sterilization* and *Radiation Sterilization Dose Audit Test reports*. The validation report demonstrates that the sterilization 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 does not affect substantially equivalency between the proposed device and predicate device.

7. Non-clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

Test	Requirements
Materials	The needle shall be made of tubing materials specified in ISO 9626.
Dimensions	The needles shall fit the test apparatus specified in item 7.3 of ISO 11608-2.

Flow rate through the needle		The needles were tested in accordance with Annex A to ISO 11608-2.
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.
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.
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.
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.
Easy 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.
Biocompatibility	Cytotoxicity	ISO 10093-5 Biological evaluation of medical devices –Part 5: Tests for in vitro cytotoxicity
	Sensitization	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization
	Irritation	ISO 10993-10 Biological evaluation of medical devices –Part 10:Tests for irritation and skin sensitization
	Haemocompatibility	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
	System toxicity (acute)	ISO 10993-11:2006/(R)2010, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
	Pyrogen	USP 34.NF 29 <151> Pyrogen Test & USP<85>.

All nonclinical testing performed on new devices demonstrate the substantial equivalence to the predicate device. Tests setup and execution are performed in accordance with applicable standards. Results of the testing are demonstrating the compliance to the standards and matching the performance of new devices to the predicate devices.

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 (K133059).