Berpu Medical Technology Co., Ltd
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K181447
Trade/Device Name: Safety insulin needle for single use
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic single lumen needle
Regulatory Class: Class II
Product Code: FMI
Dated: February 7, 2019
Received: February 12, 2019

Dear Ms. Hong:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sarah B. Mollo -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181447

Device Name
Safety insulin needle for single use

Indications for Use *(Describe)*
The safety insulin needle for single use is intended for use with pen injector devices for the 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.

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510(k) Summary

K181447

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: 01/23/2019

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Safety insulin needle for single use

Regulatory Information:
Classification Name: Hypodermic single lumen needle
Classification: II
Product Code: FMI
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital

Intended Use Statement:
The Safety insulin needle for single use is intended for use with pen injector devices for the subcutaneous injection of insulin.

Indications for Use:
The Safety insulin needle for single use is intended for use with pen injector devices for the subcutaneous injection of insulin.

Device Description

The proposed device, Safety insulin needle for single use is intended for use with pen injector devices for the subcutaneous injection of insulin. It consists of needle tube, hub, safety protective cover, self-destruction seat, spring, hub sheath, safety seat and sealed paper.

The Safety insulin needle for single use is offered in various gauge sized and length.

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

5. Identification of Predicate Device

510(k) Number: K152514
Product Name: Clickfine AutoProtect Pen Needle

6. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications in order to demonstrate that the subject device is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 7864:2016, Sterile hypodermic needles for single use.
- ISO 9626:2016, Stainless steel needle tubing for the manufacture of medical devices.
- ISO 11608-2 Second edition 2012-04-01, Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles
- ISO 10993-1:2009 Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process
- ISO 10993-4:2017, Biological Evaluation of Medical Device, Part 4: Selection of test for Interactions with Blood.
- ISO 10993-5: 2009(R), Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2006 Biological evaluation of medical devices-Part 11: Tests for systemic toxicity
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals.
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials.
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- USP <85> Bacterial Endotoxins Test

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device	Predicate Device K152514	Remark
Product Code	FMI	FMI	SE
Regulation Number	21 CFR 880.5570	21 CFR 880.5570	SE
Class	II	II	SE
Indications for Use	The Safety insulin needle for single use is intended for use with pen injector devices for the subcutaneous injection of insulin.	The Clickfine AutoProtect Pen Needle is intended for use with pen injector devices for subcutaneous injection of fluids, including insulin and exenatide. Additionally, the attached safety shield automatically locks in place and reduces the occurrence of accidental needle	SE Analysis 1

		sticks from the patient end of the needle. The shield also serves to hide the needle before and after injection.	
Configuration	Needle Tube	Needle Tube	SE Analysis 2
	Hub	Hub	
	Safety protective cover	Needle shield	
	Self-destruction seat	Housing	
	Spring	Spring	
	Hub sheath	Outer protective container	
	Safety seat	Safety lock indicator	
	Sealed paper	Peel tab	
Operation Mode	For manual use only	For manual use only	SE
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	SE

SE Analysis 1 – Indications for Use

The Indications for Use of the proposed device are different to that of predicate device. The difference is that the Indications for Use of predicate device include subcutaneous injection of exenatide while the proposed device does not. However, the indications for use of proposed device are completely included by those of the predicate. Additionally, the attached safety shield has the same role during the clinical application as that of the predicate device, although it is not expressed in the indications for use of the proposed device. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

SE Analysis 2 – Configuration

The components name of proposed device are different to that of the predicate, however, the components share the same configuration and function. Therefore, this difference in name will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Table 2 Performance Comparison

Item	Proposed Device	Predicate Device K152514	Remark
Needle Gauge	29G, 30G, 31G, 32G, 33G, 34G	29G, 30G, 31G	Analysis 3
Needle Length	4mm, 5mm, 6mm, 8mm	5mm, 6mm, 8mm	Analysis 4
Wall type	Thin-walled Extra-thin-walled	Regular walled Thin-walled	Analysis 5
Needle Performance	Complied with ISO 7864:2016,	Complied with ISO 7864: 1993	SE

	ISO 9626:2016, ISO 11608-2	ISO 9626: 1991 ISO 11608-2	

Analysis 3 – Needle Gauge

The subject device includes higher needle gauges than that of predicate devices. This difference in needle size will not raise new questions of safety and effectiveness. In addition, all the needle sizes of proposed device have been tested and met ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Analysis 4 – Needle length

The proposed device has an additional needle length than the of predicate device. This difference in needle size will not raise new questions of safety and effectiveness. In addition, all the needle lengths of the proposed device have been validated and tested and met the ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantially Equivalency (SE) between the proposed and predicate device.

Analysis 5 – Wall type

The wall thickness of the proposed device is different than the predicate device. the needles including both wall thickness (i.e. thin-walled and extra-thin-walled) of proposed device have been tested and the test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Table 3 Safety Comparison

Item	Proposed Device	Predicate Device K152514	Remark
Patient-contact material			
Hub	Polypropylene	Stainless Steel	SE Analysis 6
Needle tube	304 Stainless Steel	Polypropylene	
Safety seat	Polypropylene	Polypropylene	
Safety protective cover	MABS	MBS	
Biocompatibility			
Cytotoxicity	No cytotoxicity	Conforms to ISO 10993 series standard	SE Analysis 6
Irritation	No intracutaneous reactivity		
Sensitization	No skin sensitization		
Systemic Toxicity	No systemic toxicity		
Hemolysis	No Hemolysis		
Pyrogen	No Pyrogen		
Sterilization	EO Sterilization	Gamma irradiation	SE Analysis 7

SAL	10-6	10-6	SE
Single Use	Yes	Yes	SE
Endotoxin Limit	20EU per device	20EU per device	SE

Analysis 6 – Patient-contact Material and Biocompatibility

Although the material of proposed and the predicate device is different, the patient-contact material of the proposed device material conforms to the ISO 10993 series of standards. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Analysis 7 – Sterilization

The proposed and predicate devices are sterilized by different method. However, the sterilization parameter for proposed device was established per ISO11135 to achieve the SAL of 10-6. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis of differences above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.