Berpu Medical Technology Co., Ltd.
℅ Diana Hong
General Management
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
China

Re: K212514
Trade/Device Name: Safety Pen Needle for Single Use, Insulin Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: FMI
Dated: March 23, 2022
Received: March 30, 2022

Dear Diana 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/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 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)*
K212514

Device Name
Safety Pen Needle for Single Use
Insulin Pen Needle

Indications for Use *(Describe)*
The Safety Pen Needle for Single Use is intended for use with pen injector devices for the subcutaneous injection of insulin.

The Insulin Pen Needle 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

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

The assigned 510(k) Number: K212514

1. Date of Preparation: 04/28/2022

2. Sponsor Identification

Berpu Medical Technology Co., Ltd.
NO.14 Xingji Road, Yongxing Street, Longwan District, Wenzhou, Zhejiang, China 325000

Establishment Registration Number: 3004496829

Contact Person: Buxin Yu
Position: Management Representative
Tel: +86-577-86651999
Fax: +86-577-86630389
Email: ybx@berpu.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Tingting Su (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Safety Pen Needle for Single Use
Insulin Pen Needle
Common Name: Antistick needle and needle

Regulatory Information
Classification Name: Needle, Hypodermic, Single Lumen;
Classification: II;
Product Code: FMI;
Regulation Number: 21 CFR 880.5570
Review Panel: General Hospital

Indication for use:
The Safety Pen Needle for Single Use is intended for use with pen injector devices for the subcutaneous injection of insulin.

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

Device Description
The devices are provided in two types of configurations: Safety Pen Needle for Single Use and Insulin Pen Needle.

The Safety Pen Needle for Single Use is intended for use with pen injector devices for the subcutaneous injection of insulin. It consists of a needle cap, needle tube, needle hub, safety protective cover, self-destruction seat and sealed paper. The safety protective cover is manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

Gauge	**Length**	**Wall Type**
34G	4mm	Regular wall, Thin wall, Extra-thin wall
	5mm	Regular wall, Thin wall, Extra-thin wall
	6mm	Regular wall, Thin wall, Extra-thin wall
	8mm	Regular wall, Thin wall, Extra-thin wall
33G	4mm	Regular wall, Thin wall, Extra-thin wall
	5mm	Regular wall, Thin wall, Extra-thin wall
	6mm	Regular wall, Thin wall, Extra-thin wall
	8mm	Regular wall, Thin wall, Extra-thin wall

32G	4mm	Regular wall, Thin wall, Extra-thin wall, Ultra-thin wall
	5mm	Regular wall, Thin wall, Extra-thin wall
	6mm	Regular wall, Thin wall, Extra-thin wall
	8mm	Regular wall, Thin wall, Extra-thin wall
31G	4mm	Regular wall, Thin wall, Extra-thin wall
	5mm	Regular wall, Thin wall, Extra-thin wall
	6mm	Regular wall, Thin wall, Extra-thin wall
	8mm	Regular wall, Thin wall, Extra-thin wall
30G	4mm	Regular wall, Thin wall, Extra-thin wall
	5mm	Regular wall, Thin wall, Extra-thin wall
	6mm	Regular wall, Thin wall, Extra-thin wall
	8mm	Regular wall, Thin wall, Extra-thin wall
29G	4mm	Regular wall, Thin wall, Extra-thin wall
	5mm	Regular wall, Thin wall, Extra-thin wall
	6mm	Regular wall, Thin wall, Extra-thin wall
	8mm	Regular wall, Thin wall, Extra-thin wall

The Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin. It consists of protective cap, needle tube, needle hub, needle protective cover and sealed paper.

Gauge	**Length**	**Wall Type**
34G	4mm	Regular wall, Thin wall, Extra-thin wall
	5mm	Regular wall, Thin wall, Extra-thin wall
	6mm	Regular wall, Thin wall, Extra-thin wall
	8mm	Regular wall, Thin wall, Extra-thin wall
33G	4mm	Regular wall, Thin wall, Extra-thin wall
	4mm	Regular wall, Thin wall, Extra-thin wall
	5mm	Regular wall, Thin wall, Extra-thin wall
	6mm	Regular wall, Thin wall, Extra-thin wall
	8mm	Regular wall, Thin wall, Extra-thin wall
28G	4mm	Regular wall, Thin wall
	5mm	Regular wall, Thin wall
	6mm	Regular wall, Thin wall

	8mm	Regular wall, Thin wall
	10mm	Regular wall, Thin wall
	13mm	Regular wall, Thin wall

The proposed devices are sterilized by Ethylene Oxide Gas to achieve a SAL of 10^{-6}.

5. Identification of Predicate Device

510(k) Number: K181447
Product Name: Safety insulin needle for single use

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 10993-5: 2009 Biological evaluation of medical Devices-Part 5: Tests for in Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices- Part 10: Test for irritation and skin sensitization.
- ISO 10993-11: 2017 Biological evaluation of medical devices- Part 11: Tests for systemic toxicity
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F1886 / F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials. (Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ISO 7864:2016 Sterile hypodermic needles for single use — Requirements and test methods
- 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 23908:2011 Sharps injury protection - Requirements and test methods–Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ISO 10993-7:2008 Biological evaluation of medical devices-Part 7: Test of Ethylene Oxide Residues.
- USP<85> Bacterial Endotoxins Test
- USP<151> Pyrogen Test

Physical, Mechanical, and Chemical testing listed in following table were performed on the proposed device. The test results show that the device conforms with the requirements of related standards.

Dimensions	Clause 4.2 of ISO 11608-2:2012
Determination of flow rate through the needle	Clause 4.3 of ISO 11608-2:2012
Bond between hub and needle tube	Clause 4.4 of ISO 11608-2:2012
Needle points	Clause 4.5 of ISO 11608-2:2012
Freedom from defects	Clause 4.6 of ISO 11608-2:2012
Lubrication	Clause 4.7 of ISO 11608-2:2012
Dislocation of measuring point at patient end	Clause 4.8 of ISO 11608-2:2012
Determination of functional compatibility with needle-based injection systems	Clause 4.9 of ISO 11608-2:2012
Ease of assembly and disassembly	Clause 4.10 of ISO 11608-2:2012
Cleanliness	Clause 4.3 of ISO 7864:2016
Limits for acidity or alkalinity	Clause 4.4 of ISO 7864:2016
Limits for extractable metals	Clause 4.5 of ISO 7864:2016
Size designation	Clause 4.6 of ISO 7864:2016
Colour coding	Clause 4.7 of ISO 7864:2016
Needle hub	Clause 4.8 of ISO 7864:2016
Needle Cap	Clause 4.9 of ISO 7864:2016
Needle tube	Clause 4.10 of ISO 7864:2016
Needle point	Clause 4.11 of ISO 7864:2016
Bond between hub and needle tube	Clause 4.12 of ISO 7864:2016
Patency of lumen	Clause 4.13 of ISO 7864:2016
Surface finish and appearance	Clause 5.2 of ISO 9626:2016
Cleanliness	Clause 5.3 of ISO 9626:2016
Limits for acidity and alkalinity	Clause 5.4 of ISO 9626:2016
Size designation	Clause 5.5 of ISO 9626:2016
Dimensions	Clause 5.6 of ISO 9626:2016
Stiffness	Clause 5.8 of ISO 9626:2016
Resistance to breakage	Clause 5.9 of ISO 9626:2016
Resistance to corrosion	Clause 5.10 of ISO 9626:2016
Particulate testing	USP <788>

Package integrity testing, after environmental conditioning and simulated transportation in accordance with ASTM D4169, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection and sterility maintenance.

Sterile barrier package integrity testing was performed on the proposed devices which includes visual inspection (ASTM F1886/F1886M-16), seal strength (ASTM F88/F88-15), and dye penetration testing (ASTM F1929-15).

Sterilization and shelf life testing, listed in following table, were performed on the proposed devices. EO ECH residue did not exceed the limit of ISO 10993-7. Endotoxin limit did not exceed 20EU/device. Shelf life testing results showed that the device can maintain its performance during the claimed shelf life of 5 years.

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device

Biocompatibility testing

The contact classification of the proposed devices are Externally Communicating – Blood path, indirect for a Prolonged contact duration. The proposed devices were evaluated for the following tests. The results for the biocompatibility testing showed that there are no negative impacts from the materials that are used in the proposed devices.

- Cytotoxicity,
- Sensitization,
- Intracutaneous reactivity,
- Acute Systemic Toxicity,
- Hemolysis,
- Pyrogen,
- Subacute Toxicity

Simulated Clinical Study

A simulated clinical study was performed on proposed device according to FDA Guidance, Guidance for Industry and FDA Staff: Medical Device with Sharps Injury Prevention Feature, issued on August 9, 2005, and ISO 23908:2011 to evaluate the safety mechanism of the proposed device. The results

demonstrated that the proposed device met the pre-established criteria.

Safety Feature Test

The safety feature test was performed on the Safety Pen Needle for Single Use and predicate device to evaluate safety feature. The results demonstrated that both the proposed device and predicate device met the acceptance criteria.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technology Characteristics

Table 1 Comparison of Safety Pen Needle for Single Use

ITEM	Proposed Device K212514	Predicate Device K181447	Remark
Product	Safety Pen Needle for Single Use	Safety insulin needle for single use	/
Product Code	FMI	FMI	Same
Regulation No.	21 CRF 880.5570	21 CRF 880.5570	Same
Class	Class II	Class II	Same
Indication for Use	The Safety Pen Needle for Single Use is intended for use with pen injector devices for the subcutaneous injection of insulin.	The Safety insulin needle for single use is intended for use with pen injector devices for the subcutaneous injection of insulin.	Same
Configuration	Needle tube	Needle Tube	Different
	Needle hub	Hub	
	Safety protective cover	Safety protective cover	
	Self-destruction seat	Self-destruction seat	
	Hub sheath	Hub sheath	
	Sealed paper	Sealed paper	
	/	Safety seat	
	/	Spring	
Operation Mode	For manual use only	For manual use only	Same
Environment of use	In hospital or in the home environment	In hospital or in the home environment	Same
Method of attachment to pen injector	Through threaded connection	Through threaded connection	Same
Safety Feature	Prevent from needlestick	Prevent from needlestick	Same
Safety feature activation forces	Average at 3.71N	Average at 3.73N	Similar
Single Use	Single Use	Single Use	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Needle Gauge	29G, 30G, 31G, 32G, 33G, 34G	29G, 30G, 31G, 32G, 33G, 34G	Same
Needle Length	4mm, 5mm, 6mm, 8mm	4mm, 5mm, 6mm, 8mm	Same
Needle Performance	Complied with ISO 7864, ISO 9626, ISO 11608-2	Complied with ISO 7864, ISO 9626, ISO 11608-2	Same
Material			

Safety protective cover	Polypropylene (PP)	Polypropylene 304 Stainless Steel Polypropylene MABS	Different
Needle hub	Polypropylene (PP)		
Self-destruction seat	Polypropylene (PP)		
Hub sheath	Polypropylene (PP)		
Needle tube	Stainless Steel (SUS304)		
Sealed paper	Medical paper (Blister Paper)		
Adhesive	UV adhesive		
Lubricant	Polydimethylsiloxane		
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No skin sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Different Analysis - Configuration

The configuration of the Safety Pen Needle for Single Use is similar to the configurations of predicate device. Although the components of the proposed device and the predicate device are not identical, this difference does not affect the indication for use of the device. In addition, a series of performance tests have been conducted on the proposed device to demonstrate that the proposed device meets the requirements of the relevant standards. Therefore, it can be considered that the minor differences in the components will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Similar Analysis - Safety feature activation forces

The activation force of the Safety Pen Needle for Single Use is similar to the predicate device. The activation force difference between the two devices is 0.02N. In addition, activation force met the acceptance criteria. Therefore, the minor difference in activation force will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Different Analysis -Material

The materials for Safety Pen Needle for Single Use is different from the predicate device. However, biocompatibility testing has been performed on the proposed device and the results do not show any

adverse effect. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Table 2 Comparison of Insulin Pen Needle

ITEM	Proposed Device K212514	Predicate Device K181447	Remark
Product	Insulin Pen Needle	Safety insulin needle for single use	/
Product Code	FMI	FMI	Same
Regulation No.	21 CRF 880.5570	21 CRF 880.5570	Same
Class	Class II	Class II	Same
Indication for Use	The Insulin Pen Needle is intended for use with pen injector devices for the subcutaneous injection of insulin.	The Safety insulin needle for single use is intended for use with pen injector devices for the subcutaneous injection of insulin.	Same
Configuration	Needle tube	Needle Tube	Different
	Needle hub	Hub	
	Hub sheath	Safety protective cover	
	Needle protective cover	Self-destruction seat	
	Sealed paper	Hub sheath	
	/	Sealed paper	
	/	Safety seat	
	/	Spring	
Operation Mode	For manual use only	For manual use only	Same
Environment of use	In hospital or in the home environment	In hospital or in the home environment	Same
Method of attachment to pen injector	Through threaded connection	Through threaded connection	Same
Single Use	Single Use	Single Use	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Needle Gauge	28, 33G, 34G	29G, 30G, 31G, 32G, 33G, 34G	Different
Needle Length	4mm, 5mm, 6mm, 8mm, 10mm, 13mm	4mm, 5mm, 6mm, 8mm	Different
Needle Performance	Complied with ISO 7864, ISO 9626, ISO 11608-2	Complied with ISO 7864, ISO 9626, ISO 11608-2	Same
Material			
Needle hub	Polypropylene (PP)	Polypropylene	Different

Hub sheath	Polypropylene (PP)	304 Stainless Steel Polypropylene MABS	
Sealed paper	Medical paper (Blister Paper)		
Needle protective cover	Polypropylene (PP)		
Needle tube	Stainless Steel (SUS304)		
Adhesive	UV adhesive		
Lubricant	Polydimethylsiloxane		
Biocompatibility			
Cytotoxicity	No cytotoxicity	No cytotoxicity	Same
Irritation	No intracutaneous reactivity	No intracutaneous reactivity	
Sensitization	No sensitization	No skin sensitization	
Systemic Toxicity	No systemic toxicity	No systemic toxicity	
Hemolysis	No Hemolysis	No Hemolysis	
Pyrogen	No Pyrogen	No Pyrogen	
Sterilization			
Method	EO Sterilized	EO Sterilized	Same
SAL	10^{-6}	10^{-6}	Same
Endotoxin Limit	20 EU per device	20 EU per device	Same

Different Analysis -Configuration

The components of Insulin Pen Needle are different to that of predicate device. The proposed device does not have a safety mechanism; however, the presence or absence of a safety mechanism does not affect the indication for use and the performance of the device. In addition, a series of performance tests have been conducted on the proposed device and the results showed that the product meets the requirements of the relevant standards. Therefore, this difference does not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Different Analysis – Needle Gauge

The needle gauge of Insulin Pen Needle is different from predicate devices. The proposed 33G and 34G can be covered by the predicate device, while the proposed 28G is out of the specification range of predicate device. However, all the needle size of proposed device has been tested. The test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference does not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Different Analysis – Needle length

Compared with the predicate device, the Insulin Pen Needle has the additional 10mm and 13mm length specifications. However, these two additional length specifications have been tested. The test results comply with ISO 7864 and ISO 9626 standards requirements. Therefore, this difference does not affect the Substantial Equivalence (SE) between the proposed and predicate device.

Different Analysis -Material

The material for Safety Pen Needle for Single Use is different from the predicate device. However, biocompatibility testing has been performed on the proposed device and the results do not show any adverse effect. Therefore, this difference will not affect the Substantial Equivalence (SE) between the proposed and predicate device.

9. Substantially Equivalent (SE) Conclusion

The non-clinical tests demonstrate that the Safety Pen Needle for Single Use and Insulin Pen Needle are Substantially Equivalent (SE) to the legally marketed predicate device cleared under K181447.