August 23, 2022

Berpu Medical Technology Co., Ltd.
David Yu
Management Representative
No. 14 Xingji Road, Yongxiing Street
Wenzhou, Zhejiang 325000
China

Re: K220061
Trade/Device Name: Safety Insulin Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: July 26, 2022
Received: July 26, 2022

Dear David Yu:

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)*
K220061

Device Name
Safety Insulin Syringe

Indications for Use *(Describe)*
The Safety Insulin Syringe is a sterile, single use and non-reusable syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.

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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K220061

510kSummary

I. Submitter

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

Establishment Registration Number: 3004496829

Contact person: David Yu
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Fax: 0577-86630389
E-mail: 274269118@qq.com

Preparation date: August 23, 2022

II. Proposed Device

Trade Name of Device:	Safety Insulin Syringe
Common name:	Piston Syringe
Regulation Number:	21 CFR 880.5860
Regulatory Class:	Class II
Product code:	FMF, MEG
Review Panel	General Hospital

III. Predicate Devices

K202570	Insulin Syringe with Safety Retractable

IV .Device description

The Safety Insulin Syringe is a sterile, single use and non-reusable syringe with a permanently attached needle, which is intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse. The proposed device is available in 0.3ml, 0.5ml, 1ml volumes with a 26G-34G gauge needle. The safety feature will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The proposed device is sterilized by Ethylene Oxide to achieve a SAL of 10^{-6} and supplied in

immediate package which could maintain the sterility of the device during the shelf life of 5 years.

The proposed syringes are available in different combination of syringe volumes and/or needle sizes (refer to Table 1).

Table 1 specification of proposed device

Syringe volume	Needle sizes		
	Needle length (mm)	Needle gauge	Wall
0.3ml 0.5ml 1ml	4, 5, 6, 8, 9, 10, 12, 13	30G, 31G, 32G, 33G, 34G	RW TW ETW
0.3ml 0.5ml 1ml	4, 5, 6, 8, 9, 10, 12, 13	26G, 27G, 28G, 29G	RW TW

V. Indication for use

Characteristic	**Proposed Device** Safety Insulin Syringe K220061	**Predicate Device** Insulin Syringe with Safety Retractable K202570
Indication for Use	The Safety Insulin Syringe is a sterile, single use and non-reusable syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse.	The Insulin Syringe with Safety Retractable is a sterile, single use and non-reusable, manual retractable safety insulin syringe intended for injection of U-100 insulin into the body, while reducing the risk of sharps injuries and the potential for insulin syringe reuse

Discussions of differences in Indications for Use statement

There are only editorial differences to the indications for use statement between the predicate and the subject device which do not change the indications.

VI. Comparison of technological characteristics with the predicate devices

The comparison and discussion between the subject device and the predicate devices are listed in below table 2:

Table 2. Technological Characteristics

Item	**Proposed device (K220061)**	**Predicate device (K202570)**	**Discussion**

Prescription/over-the-counter use	Prescription Use	Prescription Use	Same
Configuration and material	1) (1) needle cap (Polypropylene)	1) Needle Cap (Polypropylene)	Same
	2) (2) needle tube (Stainless Steel 304)	2) Needle Tube (SUS304)	Same
	3) (3) Rubber piston (Polyisoprene Rubber)	3) Plunger Stopper (Polyisoprene Rubber)	It's the same component, just with a different name
	4) barrel (Polypropylene)	4) Barrel (Polypropylene)	Same
	5) plunger (Polypropylene)	5) Plunger (Polypropylene)	Same
	6) Safety protector (Polypropylene)	6) Safety-shield (Polypropylene)	It's the same component, just with a different name
	7) Fixed hub (Polypropylene)	/	Different See comment #1
	8) end cap (Polypropylene)	/	
	9) Lubricant (Polydimethylsiloxane)	unknown	
	10) Adhesive (UV Curing Adhesive)	unknown	
Size	0.3ml, 0.5ml, 1ml	0.5ml, 1ml	Different- See comment # 2
Needle Gauge	26G to 34G	27G to 31G	
Needle Length (mm)	4, 5, 6, 8, 9, 10, 12, 13	1/2", 5/16", 1/4"	
Wall type	RW, TW, ETW	/	

Needle performance	ISO 9626 ISO 7864	ISO 9626 ISO 7864	Same
Syringe performance	ISO 8537	ISO 8537	Same
Safety feature performance	The force to activate the safety mechanism is less than 5N The force that the safety mechanism is destroyed is greater than 20N	In-Safe mode force: not be more than 5N Resist force: 60s with 20N weights, and the protective device shall not be opened	Difference See comment # 3
Intended user population	Adult and Pediatric	Adult and Pediatric	Same

Discussions of differences in technological characteristics

Comment# 1

The configurations and raw materials of Safety Insulin Syringe are different from predicate device. These differences do not raise new questions of safety or effectiveness. The biocompatibility for the subject device has been evaluated and the results comply with the requirements of ISO 10993.

Comment# 2

The needle gauge and length for proposed devices is different from the predicate devices. The differences do not raise new questions of safety or effectiveness.

Comment# 3

The Safety feature performance specification for predicate device is a little difference. The safety mechanism of proposed device is implemented by the upper and lower buckle of the vertical axis (After the injection is completed, manually pull the safety protector toward the needle tip until it cannot slide anymore, the protection mechanism is triggered, the safety protector can't return, and the needle tube is completely protected by the safety protector), while the safety mechanism of predicate device is implemented by the convex points of the vertical axis + horizontal axis. However, the safety feature performance test for proposed device has been evaluated and the test result conforms to requirements of ISO 23908:2011 standards. Therefore, the differences on configuration and materials does not affect substantially equivalence.

VII .Non-Clinical Testing

The sterile single lumen hypodermic needles described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices- Requirements and methods
- ISO 7864:2016 Sterile hypodermic needles for single use-Requirements and test methods
- ISO 8537: 2016 Sterile single-use syringes, with or without needle, for insulin.
- ISO 23908- First edition: Sharps injury protection- Requirements and test methods-Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Biocompatibility Testing:

In accordance with ISO 10993-1, the needle is classified as: Externally Communicating Device, Blood Path Indirect, Prolonged Contact (>24hours to 30days). The following testing was conducted:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Acute systemic toxicity
- Pyrogenicity
- Hemocompatibility
- Subacute Systemic Toxicity

Particulate Testing, USP<788>

Sterility, Shipping and Shelf Life

The sterilization method has been validated per ISO 11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Safety Insulin Syringe is 5 years, determined based on stability studies which includes accelerated aging.

Sterilization and shelf life testing listed were performed on the proposed device.

Item	Standard
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. Shelf-Life of 5 years is validated using ASTM F1980-16

- Simulated transportation Test was conducted in accordance with ASTM D4169-16 used final packaged sterile device after accelerated aging, which were stored for 72 hours under the environment of temperature and humidity (-35 °C±2°C, 24 hours, 40°C±2°C, 90%RH±5%RH, 24 hours, 60°C±2°C, 24 hours).

- Sterile Barrier Packaging Testing performed on the proposed device:
  - Visual Inspection in accordance with ASTM F1886 / F1886M-16
  - Seal Strength in accordance with ASTM F88/F88M-15
  - Dye Penetration in accordance with ASTM F1929-15

Simulated Clinical Use

A simulated clinical use study was performed on 500 device samples for the safety insulin syringe 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 to evaluate the safety mechanism of the proposed device. The results demonstrated that the proposed device met the pre-established criteria.

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristics as the predicate device. Performance testing data demonstrates that the proposed device is substantially equivalent. Accordingly, the proposed device is substantially equivalent to the predicate device.