Berpu Medical Technology Co., Ltd
Buxin Yu
Official Correspondent
No. 14 Xingji Road, Yongxing Street, Longwan District
Wenzhou, Zhejiang 325000
China

Re: K221045
Trade/Device Name: Insulin Syringes without needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF
Dated: October 6, 2022
Received: October 6, 2022

Dear Buxin 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,

For CAPT. Alan M. 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)*
K221045

Device Name
Insulin Syringes without needle

Indications for Use *(Describe)*
The Insulin Syringes without needle is intended for medical purpose in conjunction with sterile needle for the manual aspiration and injection of U100 insulin into subcutaneous tissues.

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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# K221045
# 510(k) Summary

**Submitter:**

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
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E-mail: 274269118@qq.com

Preparation date: October 31, 2022

**Device Regulation:**

| | |
|---|---|
| Trade Name of Device: | Insulin Syringes without needle |
| Common name: | Piston Syringe |
| Regulation Number: | 21 CFR 880.5860 |
| Regulatory Class: | Class II |
| Product code: | FMF |
| Review Panel | General Hospital |

**Predicate Device:**

| | |
|---|---|
| 510(k) Number: | K162180 |
| Trade name: | Disposable Insulin Syringe |
| Common name: | Piston Syringe |
| Classification: | Class II |
| Product Code: | FMF |
| Manufacturer: | Berpu Medical Technology Co., Ltd |

**Device Description:**

The Insulin Syringes without needle is a sterile and single use syringe intended for injection of U-100 insulin into the body, in conjunction with a sterile needle. The proposed device is available in 1 ml.

The proposed device is sterilized by Ethylene Oxide to achieve a SAL of $10^{-6}$ and supplied in immediate package to maintain the sterility of the device during the shelf life of 5 years.

Insulin Syringes without needle materials of construction are as provided in Table 1 below. For other device characteristics please refers to Table 2.

**Table 1** Materials of Insulin Syringes without needle

| Part name | Material |
|---|---|
| Plunger | Polypropylene (PP) |
| Barrel | Polypropylene (PP) |
| Piston | Polyisoprene Rubber |
| Lubricant | Polydimethylsiloxane |

**Table 2** Insulin Syringes without needle characteristics

| Items | Proposed device |
|---|---|
| Intended users | Adults and Pediatrics |
| Mechanism of action | The needle tube is punctured into body for insulin injection operation, the insulin will flow into body due to the pull force of plunger. |
| Environment of use | Prescription use |
| Single use | Yes |
| Volume | 1 ml |

**Indications for Use:**

The Insulin Syringes without needle is intended for medical purpose in conjunction with sterile needle for the manual aspiration and injection of U100 insulin into subcutaneous tissues.

**Comparison of Technological Characteristics with the Predicate Device:**

The comparison and discussion between the subject device and the predicate device is listed in Table 3 below:

**Table 3** General Comparison of Insulin Syringes without needle

| Item | Proposed device | Predicate device (K162180) | Discussion |
|---|---|---|---|
| Product name | Insulin Syringes without needle | Disposable Insulin Syringe | - |
| Product Code | FMF | FMF | Same |
| Regulation No. | 21 CFR 880.5860 | 21 CFR 880.5860 | Same |
| Class | II | II | Same |

| | | | |
|---|---|---|---|
| Indication for use | The Insulin Syringes without needle is intended for medical purpose in conjunction with sterile needle for the manual aspiration and injection of U100 insulin into subcutaneous tissues. | The disposable insulin syringe is intended for medical purposes for the manual aspiration of U-100 insulin, and for the injection of insulin into parts of the body below the surface skin. | Same |
| Environment of use | Prescription Use | Prescription Use | Same |
| Intended users | Adults and Pediatrics | Adult and Pediatric | Same |
| Materials of Construction | (1) Plunger (PP)<br>(2) Barrel (PP)<br>(3) Piston (Polyisoprene Rubber)<br>(4) Lubricant (Polydimethylsiloxane) | (1) Protective end cap (PP)<br>(2) Needle (Stainless Steel 304)<br>(3) Piston (Polyisoprene Rubber)<br>(4) Plunger (PP)<br>(5) Barrel (PP)<br>(6) Lubricant (Polydimethylsiloxane) | Difference[1] |
| Size | 1ml | 0.3ml, 0.5ml, 1ml | Difference[2] |
| Method of attachment to needle | Luer lock | Permanently attached needle | Difference[3] |
| Shelf life | 5 years | 5 years | Same |
| Syringe performance | Complied with ISO 8537, ISO 80369-7 | Complied with ISO 8537, ISO 9626, ISO 7864. | Difference[4] |
| Biocompatibility | Conforms to the requirements of ISO 10993 series standards. | Conforms to the requirements of ISO 10993 series standards. | Same |
| Method | EO Sterilized | EO Sterilized | Same |
| SAL | $10^{-6}$ | $10^{-6}$ | Same |
| Operation Principle | For Manual Use Only, For Single Use Only | For Manual Use Only, For Single Use Only | Same |
| Label/Labeling | Complied with 21 CFR part 801 | Complied with 21 CFR part 801 | Same |

[1] The subject syringes' materials are same as the predicate device (K162180) except that the subject syringe does not have a needle. Therefore, the differences on configuration and materials of construction do not raise new questions about safety and effectiveness.

[2] The size for subject device is different from the predicate device. However, predicate device's size range covers that of subject device. Therefore, the differences in size do not raise new questions about safety and effectiveness.

[3] The method of attachment to needle is different for proposed device and predicate device. Proposed device connection method with needle is luer lock. The needle is permanently attached with nozzle in predicate device. The performance test according to ISO 80369-7:2021 have been conducted with proposed device. Therefore, the differences on method of attachment to needle do not raise new questions about safety and effectiveness.

[4] Proposed device and predicate device are complied with the insulin syringes standard ISO 8537:2016. Therefore, the difference on performance tests due to the method of attachment to needle do not raise new questions about safety and effectiveness.

**Non-Clinical Testing:**

The Insulin syringes without needle described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 8537: 2016, Sterile single-use syringes, with or without needle, for insulin.
- ISO 80369-7:2021 Second edition, Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications

**Biocompatibility Testing:**

In accordance with ISO 10993-1, the syringe is classified as: Externally Communicating Device, Blood Path Indirect, Prolonged Contact (>24hours to 30days). The following biocompatibility endpoints were addressed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Subchronic/Subacute Toxicity
- Hemocompatibility

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections - Method 1: Light Obscuration Particle Count Test and met the USP acceptance criteria.

**Sterility, Shipping and Shelf Life:**

The sterilization method has been validated per ISO 11135: 2014 Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices. The shelf life of the Insulin syringes without needle is 5 years, determined

based on stability studies which includes accelerated aging and simulated shipping.

Sterilization shelf-life studies were conducted in compliance with the following standards:

| Item | Standard |
|---|---|
| EO and ECH residuals | ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals |
| Bacteria Endotoxin Limit | USP <85> Bacterial Endotoxins |
| Shelf-Life Evaluation | Shelf life of 5 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices |

- Package integrity testing, after accelerated aging, environmental conditioning and simulated transportation in accordance with ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.
- 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

**Clinical Testing**

No clinical study is included in this submission.

**Conclusion**

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The Insulin Syringes without needle is substantially equivalent to the Disposable Insulin Syringe with respect to the indications for use, target populations, treatment method, and technological characteristics.