May 12, 2022

BERPU MEDICAL TECHNOLOGY CO., LTD
Buxin Yu
Management Representative
No.14 Xingii Road, Yongxing Street
Longwan District, 325000, Wenzhou, Zhejiang
Province

Re: K213811
Trade/Device Name: Sterile Hypodermic Syringes For Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: FMF
Dated: February 2, 2022
Received: April 4, 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 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)*
K213811

Device Name
Sterile Hypodermic Syringe for Single Use

Indications for Use *(Describe)*
The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purposes on adult and pediatric population to inject fluids into or withdraw fluids from the body.

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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"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."

K213811 510(k) Summary

1. **Date of Preparation:** May 7, 2022

2. **Sponsor Identification**

BERPU MEDICAL TECHNOLOGY CO., LTD
NO.14 Xingji Road, Yongxing Street, Longwan District, 325000, Wenzhou, Zhejiang Province

Establishment Registration Number: 3004496829

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

3. **Identification of Proposed Device**

Trade Name: Sterile Hypodermic Syringe for Single Use

Regulatory Information
Classification Name: Piston Syringe
Classification: II
Product Code: FMF
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

4. **Identification of Predicate Devices**

Predicate Device
510(k) Number: K210227
Product Name: Sterile syringe for single use with/without needle

5. **Device Description**

The Sterile Hypodermic Syringe for Single Use is intended for single use only, which consists of barrel, plunger and piston. The proposed device is available in a variety syringe volume. The syringe is available in luer slip and luer lock two connector types which are intended to be connected with a hypodermic needle.

6. Indication for Use

Characteristic	**Predicate Device** Sterile syringe for single use with/without needle **K210227**	**Subject Device** Sterile Hypodermic Syringes for Single Use **K213811**
Indication for Use	The Sterile Syringes for Single Use with/without needle are intended to be used for medical purposes on adult and peto inject fluids into or withdraw fluids from the body.	The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purposes on adult and pediatric population to inject fluids into or withdraw fluids from the body.

The indications for use of the subject device are slightly different from the predicate device. The difference is the intended population is included in the indications of subject device. This difference is does not affect safety and effectiveness of the proposed device.

7. Substantially Equivalent (SE) Comparison

Table 2 Comparison of Technology Characteristics of Sterile Hypodermic Syringes for Single Use

Item	**Proposed Device K213811**		**Predicate Device K210227**		**Remark**
Product name	Sterile Hypodermic Syringes for Single Use		Sterile syringe for single use with/without needle		-
Product Code	FMF		FMF		same
Regulation No.	21 CFR 880.5860		21 CFR 880.5860		Same
Class	CLASS II		CLASS II		same
Syringe volume	10ml, 20ml, 30ml, 50mL, 60ml		1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 60ml, 100ml		Analysis 1
Nozzle type	Luer slip; Luer lock		Luer slip; Luer lock		same
Configuration and material	Barrel	Polypropylene (PP)	Barrel	Polypropylene (PP)	Analysis 2
	Plunger	Polypropylene (PP)	Plunger	Polypropylene (PP)	
	Piston	Polyisoprene Rubber	Piston	Silicone Rubber	
Operation Mode	For manual use only		For manual use only		same
Syringe Performance	Complied with ISO 7886-1:2017		Complied with ISO 7886-1:2017		same
Biocompatibility	Comply with ISO 10993 series standards, which includes:		Comply with ISO 10993 series standards, which includes:		same

	ISO 10993-5: 2009; ISO 10993-10: 2010 ISO 10993-4: 2017 ISO 10993-11: 2017	ISO 10993-5: 2009; ISO 10993-10: 2010 ISO 10993-4: 2017 ISO 10993-11: 2017	
OTC use	No	No	same
Single for Use	Yes	Yes	same
Patient population	Adult and children	unknown	Analysis 3
Shelf-life	5 years	3 years	Analysis 4
Sterilization	EO Sterilization	EO Sterilization	same
SAL	10^{-6}	10^{-6}	same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	same

Analysis 1- Syringe volume

The proposed has less specification of syringe volume compared to predicate device. However, the different syringe volume will be selected by physician per injection requirement and this difference does not affect intended use. In addition, the syringe volume for proposed device is covered by predicate device. The performance of the proposed devices has been performed on the final finished device. The test results shows passed the requirements of standard of ISO 7886-1. Therefore, this difference is not considered to affect the Substantially Equivalency (SE) between the proposed and predicate devices.

Analysis 2-Configuration and material

The configurations for both proposed device and predicate device are similar, the difference is just in component material. However, the biocompatibility test result does not show any adverse effect which can demonstrate the safety of proposed device. Therefore, this difference is not considered to affect substantially equivalence.

Analysis 3-Paptient population

This difference does not alter suitability of the proposed device for its intended use

Analysis 4-Shelf-life

The shelf life of the proposed device is 5 years, which is longer than the predicated device. The product performance after 5 years has been determined based on accelerated aging study. The packaging integrity test of proposed device was conducted on the proposed device. The results can demonstrate that the packaging was able to maintain sterility of the sterilized finished device during its shelf life of 5 years.

8. Non-Clinical Test Performance Testing

The Sterile Hypodermic Syringe for Single Use described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7886 -1:2017 Sterile hypodermic syringes for single use — Part 1: Syringes for manual use

- ISO 80369-7: 2016 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, Limited Contact (<24hours). The proposed device was 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 device.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity Test
- Acute Systemic Toxicity
- Hemocompatibility
- Pyrogenicity

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

Sterile Barrier Packaging Test

Sterile barrier packaging testing were performed on the proposed device, which include visual inspection (ASTM F1886/F1886M-16), seal strength (ASTM F88/F88-15) and dye penetration test (ASTM F1929-15). The test result showed that the device package can maintain its integrity.

Sterilization and Shelf Life Test

The sterilization method has been validated per ISO 11135, which has thereby determined the routine control and monitoring parameters. The shelf life of the Sterile Hypodermic Syringe for Single Use 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

9. Conclusion

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