August 9, 2018

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

Re: K180417
Trade/Device Name: Self-destruction Safety Syringes for Single Use; Sterile Hypodermic Syringes for Single Use; Sterile Hypodermic Needles for Single Use; Sterile Safety Hypodermic Needles for Single Use
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: MEG, FMF, FMI
Dated: July 18, 2018
Received: July 30, 2018

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/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,

Alan M. Stevens -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

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)*
K180417

Device Name
Self-destruction Safety Syringes for Single Use; Sterile Hypodermic Syringes for Single Use; Sterile Hypodermic Needles for Single Use; Sterile Safety Hypodermic Needles for Single Use

Indications for Use *(Describe)*
The Self-destruction Safety Syringes for Single Use are intended to be used for medical purposes to inject fluid into or withdraw fluid from body. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.

The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

The Sterile Hypodermic Needles for Single Use are intended to be used with a luer slip or luer slip syringe and injection devices for general purpose fluid injection/aspiration.

The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer slip syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

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

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

The assigned 510(k) Number: K180417

1. Date of Preparation: 08/08/2018

2. Sponsor Identification

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

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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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: Self-destruction Safety Syringes for Single Use
Sterile Hypodermic Syringes for Single Use
Sterile Hypodermic Needles for Single Use
Sterile Safety Hypodermic Needles for Single Use

Regulatory Information

Classification Name: Piston Syringe
Classification: II
Product Code: MEG (antistick syringe)
Regulation Number: 21 CFR 880.5860
Review Panel: General Hospital

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

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 Self-destruction Safety Syringes for Single Use are intended to be used for medical purposes to inject fluid into or withdraw fluid from body. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.

The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

The Sterile Hypodermic Needles for Single Use are intended to be used with a luer slip or luer slip syringe and injection devices for general purpose fluid injection/aspiration.

The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer

slip syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Device Description

The Self-destruction Safety Syringes for Single Use are intended for single use only. The proposed device is available in 1mL, 3mL, 5mL, 10mL volumes with a 25 gauge, 25mm needle. The safety feature will be manually activated to retract the needle immediately after use to minimize risk of accidental needle sticks.

The Sterile Hypodermic Syringes for Single Use are intended for single use only, which consists of barrel, plunger and piston. The proposed device is available in 1mL, 2mL, 3mL, 5mL, 10mL, 20mL, 30mL and 50mL volumes. The syringe is available in luer slip or luer lock connector types which are intended to be connected with a hypodermic needle.

The Sterile Safety Hypodermic Needles for Single Use are intended for single use only, which consists of a hypodermic needle with a safety sheath attached to the needle hub. The proposed device is available in 18-27 gauge and 6-50 mm lengths. The safety sheath will be manually activated to cover the needle immediately after use to minimize risk of accidental needle sticks.

The Sterile Hypodermic Needles for Single Use are intended for single use only. The proposed device is available in 14-30 gauge and 6-60 mm lengths.

5. Identification of Predicate and Reference Devices

Predicate Device 1
510(k) Number: K072739
Product Name: Retractable Auto-Disable Syringe for Single Use, with/without Needle
Sterile Hypodermic Needle for Single Use
Sterile Hypodermic Syringe for Single Use with/without Needle

Predicate Device 2
510(k) Number: K113422
Product Name: TERUMO® SurGuard® 3 Safety Needle

Reference Device
510(k) Number: K162180
Product Name: Disposable Insulin Syringe

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and is Substantially Equivalent (SE) to the predicate device. The test results demonstrate conformance with the related standard requirements and include the following:

Physical, Mechanical, Chemical testing were performed on all syringe volumes of Self-destruction Safety Syringes for Single Use and Sterile Hypodermic Syringes for Single Use, the test items include:

Cleanliness	Clause 5 of ISO 7886-1:1993
Limits for acidity or alkalinity	Clause 6 of ISO 7886-1:1993
Limits for extractable metals	Clause 7 of ISO 7886-1:1993
Lubricant	Clause 8 of ISO 7886-1:1993
Tolerance on graduated capacity	Clause 9 of ISO 7886-1:1993
Graduated scale	Clause 10 of ISO 7886-1:1993
Barrel	Clause 11 of ISO 7886-1:1993
Piston/ plunger assembly	Clause 12 of ISO 7886-1:1993
Nozzle	Clause 13 of ISO 7886-1:1993
Performance	Clause 14 of ISO 7886-1:1993
Gauging	Clause 4.1 of ISO 594-2:1998
Leakage	Clause 4.2 of ISO 594-2:1998
Separation force	Clause 4.3 of ISO 594-2:1998
Unscrewing torque	Clause 4.4 of ISO 594-2:1998
Ease of assembly	Clause 4.5 of ISO 594-2:1998
Resistance to overriding	Clause 4.6 of ISO 594-2:1998
Stress cracking	Clause 4.7 of ISO 594-2:1998
For Safety syringe:	
Safety Feature	ISO 23908

Physical, Mechanical, Chemical testing were performed on all needle gauges and lengths of Sterile Hypodermic Needles for and Single Use Sterile Safety Hypodermic Needles for Single Use, the test items include:

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 and ISO 6009
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	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
For Safety needle:	
Safety Feature	ISO 23908

Sterile Barrier Packaging Testing performed on the proposed device:

Seal strength	ASTM F88/F88-15
Dye penetration	ASTM F1929-15

Sterilization and Shelf Life Testing performed on the proposed device:

EO residue	ISO 10993-7:2008
ECH residue	ISO 10993-7:2008
Bacteria Endotoxin Limit	USP 38-NF 33 <85>
Shelf Life Evaluation	Physical, Mechanical, Chemical, Package Tests were performed on aging samples to verify the claimed shelf life of the device

1ml Self-destruction Safety Syringes for Single Use, 1ml Sterile Hypodermic Syringes for Single Use, 27G×20mm Sterile Safety Hypodermic Needles for Single Use and 30G×12mm Sterile Hypodermic Needles for Single Use are used for sterilization validation test.

The shelf life validation test was performed on syringe from 1ml to 50ml and needle gauge from 14G~30G with 6~60mm length

Biocompatibility Testing:

The devices meet biocompatibility endpoints for cytotoxicity, irritation, sensitization, systemic toxicity, hemolysis and material-mediated pyrogens. The data was supplied in the reference device submission, K162180, and the manufacturer certified that the devices, in their final finished form, are identical to the K162180 reference device (cleared 12/29/2016) in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Simulated Clinical Use

A simulated clinical use study was performed on 500 device samples each for the safety syringe and safety needles 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.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics of Self-destruction Safety Syringes for Single Use

ITEM	Proposed Device		Predicate Device 1 K072739	
Product Code	MEG		Same	
Regulation No.	21 CFR 880.5860		Same	
Class	CLASS II		Same	
Intended Use	The Self-destruction Safety Syringes for Single Use are intended to be used for medical purposes to inject fluid into or withdraw fluid from body. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.		The Retractable Auto-Disable Syringe for single use with/without needle is intended to be used for medical purposes to inject fluid into or withdraw fluid from body. Its secondary intended use is to retract inside the safety barrel, contain the contaminated needle and aid in the prevention of accidental needle stick injuries.	
Configuration and material	Barrel	Polypropylene (PP)	Barrel	PP, Stainless Steel
	Plunger	Polypropylene (PP)	Plunger	
	Piston	Polyisoprene	Piston	
	Needle hub	Polypropylene (PP)	Needle hub	
	Needle tube	Stainless Steel	Needle tube	
Operation Mode	For manual use only		Same	
Safety Feature	Retracted		Same	
Label/Labeling	Comply with 21 CFR part 801		Same	
Syringe Volume	1ml, 3ml, 5ml, 10ml		3ml, 5ml, 10ml	
Connector Type	Luer Lock		Same	
Needle Gauge	25G		Unknown	
Biocompatibility	Comply with ISO 10993		Same	
Sterilization	EO Sterilization		Same	
SAL	10^{-6}		Same	
Single Use	Yes		Same	
Label/Labeling	Complied with 21 CFR part 801		Same	

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

ITEM	Proposed Device		Predicate Device 1 K072739	
Product Code	FMF		Same	
Regulation No.	21 CFR 880.5860		Same	
Class	CLASS II		Same	
Intended Use	The Sterile Hypodermic Syringes for Single Use are intended to be used for medical purpose to inject fluid into or withdraw fluid from body.		The Sterile Hypodermic Syringe for Single Use with/without needle is intended to be used for medical purpose to inject fluid into or withdraw fluid from body	
Configuration and material	Barrel	Polypropylene (PP)	Barrel	PP
	Plunger	Polypropylene (PP)	Plunger	
	Piston	Polyisoprene	Piston	
Operation Mode	For manual use only		Same	
Label/Labeling	Complied with 21 CFR part 801		Same	
Syringe Volume	1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml		1ml, 2ml, 3ml, 5ml, 10ml, 20ml, 30ml, 50ml, 100ml	
Connector Type	Luer Lock/ Luer slip		Same	
Biocompatibility	Comply with ISO 10993		Same	
Sterilization	EO Sterilization		Same	
SAL	10^{-6}		Same	
Single Use	Yes		Same	
Label/Labeling	Comply with 21 CFR part 801		Same	

Table 3 Comparison of Technology Characteristics of Sterile Hypodermic Needles for Single Use

ITEM	Proposed Device		Predicate Device 1 K072739	
Product Code	FMI		Same	
Regulation No.	21 CFR 880.5570		Same	
Class	CLASS II		Same	
Intended Use	The Sterile Hypodermic Needles for Single Use are intended to be used with a luer slip or luer slip syringe and injection devices for general purpose fluid injection/aspiration.		The Sterile Hypodermic Needle for single use is intended for use with syringes and injection devices for general purpose fluid injection/aspiration.	
	Needle hub	Polypropylene (PP)	Needle hub	PP, Stainless Steel
	Protective cap	Polypropylene (PP)	Protective cap	
	Needle	Stainless Steel	Needle tube	
Operation Mode	For manual use only		Same	
Label/Labeling	Complied with 21 CFR part 801		Same	
Needle Gauge	Available in14G, 15G, 16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G, 30G		Available in 16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 29G	
Biocompatibility	Comply with ISO 10993		Same	
Sterilization	EO Sterilization		Same	
SAL	10^{-6}		Same	
Single Use	Yes		Same	
Label/Labeling	Comply with 21 CFR part 801		Same	

Table 4 Comparison of Technology Characteristics of Sterile Safety Hypodermic Needles for Single Use

ITEM	Proposed Device		Predicate Device 1 K113422	
Product Code	FMI		Same	
Regulation No.	21 CFR 880.5570		Same	
Class	CLASS II		Same	
Intended Use	The Sterile Safety Hypodermic Needles for Single Use are intended to be used with a luer slip or luer slip syringe for aspiration and injection of fluids for medical purpose. After withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.		The TERUMO® SurGuard® 3 Safety Needle is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO® SurGuard® 3 Safety Needle is compatible for use with standard luer slip and luer lock syringes.	
	Needle hub	Polypropylene (PP)	Needle hub	Unknown
	Protective cap	Polypropylene (PP)	Protective cap	
	Needle	Stainless Steel	Needle tube	
	Safety sheath	Polypropylene (PP)	Safety sheath	
Operation Mode	For manual use only		Same	
Safety Feature	Slide over the needle to prevent from needle sticks		Same	
Label/Labeling	Comply with 21 CFR part 801		Same	
Needle Gauge	Available in 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G		18G~25G	
Biocompatibility	Comply with ISO 10993		Same	
Sterilization	EO Sterilization		Irradiation Sterilization	
SAL	10^{-6}		Same	
Single Use	Yes		Same	
Label/Labeling	Complied with 21 CFR part 801		Same	

9. Substantially Equivalent (SE) Conclusion

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