July 21, 2022

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

Re: K213158
Trade/Device Name: Syringe with permanently attached needle
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: FMF, MEG
Dated: June 14, 2022
Received: June 21, 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)*
K213158

Device Name
Syringe with permanently attached needle

Indications for Use *(Describe)*
Syringe with permanently attached needle
The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

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.

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510(k) summary

The assigned 510(k) Number: K213158

I Submitter

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

Establishment Registration Number: 3004496829

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Position: Management representative
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Preparation date: July 17, 2022

II Proposed Device

Trade Name of Device:	Syringe with permanently attached needle
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

510(k) Number:	K192551
Trade name:	Syringe with permanently attached needle
Common name:	Piston Syringe
Classification:	Class II
Product Code:	FMF, MEG

Manufacturer Jiangsu Caina Medical Co., Ltd.

IV Device description

The Syringe with permanently attached needle is intended for single use only. The proposed device is available in 0.3ml, 0.5ml, 1ml volumes with a 20G-34G gauge needle.

The product is for single use and provided sterile (EtO). The shelf-life of the product is five-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

Device	Needle length (mm)	Needle gauge	Needle wall type	Syringe size/volume
Syringe with permanently attached needle Specification	4, 5, 6, 8, 9, 10, 12, 13, 16, 20	34G 33G	RW TW ETW	0.3ml 0.5ml 1ml
	4, 5, 6, 8, 9, 10, 12, 13, 16, 20, 22, 25, 28, 32	32G 31G	RW TW ETW	0.3ml 0.5ml 1ml
	4, 5, 6, 8, 9, 10, 12, 13, 16, 20, 22, 25, 28, 32, 35, 38, 40	30G 29G 28G 27G 26G 25G 24G 23G 22G 21G 20G	RW TW ETW	0.3ml 0.5ml 1ml

V Indication for use

Syringe with permanently attached needle

The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.

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 General Comparison of Syringe with permanently attached needle

Item	**Proposed device**	**Predicate device (K192551)**	**Discussion**
Product name	Syringe with permanently attached needle	Syringe with permanently attached needle	same
Product Code	FMF	FMF	same
Regulation No.	21 CFR 880.5860	21 CFR 880.5860	same
Class	II	II	same
Indication for use	The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.	The Syringe with permanently attached needle is intended for use by health care professionals for general purpose aspiration of fluid from vials, ampoules and liquid injection below the surface of the skin.	same
Prescription/over-the-counter use	Prescription Use	Prescription Use	Same
Configuration and material	(1) needle cap (PP) (2) needle (Stainless Steel 304) (3) piston (Polysoprene Rubber) (4) plunger (PP) (5) barrel (PP)	(1) needle cap (PP or PE) (2) needle (Stainless Steel 304) (3) piston (Polysoprene) (4) plunger (PP) (5) barrel (PP)	Similar[1]

Syringe Volume	0.3ml, 0.5ml, 1ml	0.3ml, 0.5ml, 1ml	Same
Needle Gauge	20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G	21G, 23G, 25G, 26G, 27G, 28G, 29G, 30G, 31G	Difference[2]
Needle Length (mm)	4, 5, 6, 8, 9, 10, 12, 13, 16, 20, 22, 25, 28, 32, 35, 38, 40	8, 10, 13, 16, 20, 25	
Needle wall type	RW, TW, ETW	RW, TW	
Needle performance	ISO 9626 ISO 7864	ISO 9626 ISO 7864	Same
Syringe performance	ISO 7886-1	ISO 7886-1	Same
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 configurations of Syringe with permanently attached needle are same as the configuration of predicate device, but there are some differences in raw materials. The differences on configuration and materials do not raise new questions about safety and effectiveness. Additionally, the proposed syringes' biocompatibility can be demonstrated by the reference device (K162180).

[2] The needle gauge and length for proposed devices is different from the predicate devices. However, this difference is just in dimension. Different size and length device will be selected by physician per patient's condition. This difference does not affect intended use, differences in needle length and gauge between the predicate and subject device were addressed through ISO 7864:2016 and ISO 9626:2016 performance testing. The needle wall type for predicate device is unknown. However, the performance test for proposed device has been conducted and the test result

conform with requirements of ISO 7864:2016 and ISO 9626:2016 standards. The needle bevel for proposed devices are different from the predicate device 2. However, this difference is just in dimension. Different needle bevel will be selected by physician per patient's condition. This difference does not affect intended use. In addition, differences in needle bevel between the predicate and subject device were addressed through ISO 7864:2016 and ISO 9626:2016 performance testing. Therefore, the differences on needle length, gauge, wall type and bevel does not affect substantially equivalence on safety and effectiveness.

VII Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications as was 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
- ISO 7886-1:2017 Sterile hypodermic syringes for single use- Part 1: Syringes for manual use.
- ISO 9626:2016, Stainless Steel Needle Tubing for the Manufacture of Medical Devices.
- ISO 7864:2016 Sterile hypodermic needles for single use — Requirements and test methods
- ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals.
- USP 41-NF36:2018<85> Bacterial Endotoxin Limit
- USP <788> Particulate Matter in injections
- 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
- ASTM F1886/F1886M-16, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

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).

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 characteristic as the predicate device. Performance testing data demonstrates that the proposed device is as safe and as effective as the predicate device. Accordingly, the proposed device is substantially equivalent to the predicate device.