September 15, 2023

Poonglim Pharmatech Inc.
℅ Peter Chung
President
Plus Global
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K221860
Trade/Device Name: PLPT LDV(Low Dead Volume) LC(Luer-Cone) Sterile Syringe, PLPT LDV(Low Dead Volume) LL(Luer-Lock) Sterile Syringe
Regulation Number: 21 CFR 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNG, QNS, FMI
Dated: September 1, 2023
Received: September 5, 2023

Dear Peter Chung:

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,

Courtney Evans -S

Digitally signed by Courtney Evans -S
Date: 2023.09.15 22:15:47 -04'00'

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)*
K221860

Device Name
PLPT LDV(Low Dead Volume) LL(Luer-Lock) Sterile Syringe;
PLPT LDV(Low Dead Volume) LC(Luer-Cone) Sterile Syringe

Indications for Use *(Describe)*
PLPT LDV (Low Dead Volume) LC(Luer-Cone) Sterile Syringe / PLPT LDV (Low Dead Volume) LL(Luer-Lock) Sterile Syringe 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
K221860
[as required by 807.92(c)]

1. Date of Preparation: September 12, 2023

2. Applicant

1) Company: Poonglim Pharmatech Inc.
2) Address: 21, Jayumuyeok 1-Gil, Gunsan, 54001, Republic of Korea
3) Tel : +82-63-451-8141
4) Fax : +82-63-451-8145
5) Contact person : Peter Chung, 412-512-8802
6) Contact person address : 300 Atwood Street, Pittsburgh, PA, 15213, USA
7) Submission date: September 12, 2023

3. Subject Device Information

1) Trade name : PLPT LDV(Low Dead Volume) LC(Luer-Cone) Sterile Syringe; PLPT LDV(Low Dead Volume) LL(Luer-Lock) Sterile Syringe
2) Common name : Disposal syringe
3) Classification name : Low Dead Space Piston Syringe
4) Product code : QNQ
5) Regulation number : 21 CFR 880.5860
6) Class of device : Class II
7) Panel : General hospital

4. Predicate/Reference Device

4.1 Predicate device

1) Trade name (Predicate Submission Number):
   (1) PLPT LDV (Low Dead Volume) Sterile Syringe (K210443)
   (2) EZ-Injec LDV Sterile Safety Needle (K210444)

2) Manufacturer: Poonglim Pharmatech Inc.

4.2 Reference device

1) Trade name
   (1) EZ-Injec Single Use Needle (K192222)
2) Manufacturer: Poonglim Pharmatech Inc.

5. Device description

PLPT LDV LC Sterile Syringe / PLPT LDV LL Sterile Syringe is a device intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a calibrated barrel (cylinder) with plunger, and metal tube that is sharpened at one end and at the other end joined to a female connector (hub). This device is intended for various medical applications and is not dedicated to medication administration. At the distal end of the barrel has a Luer-Cone or Luer-lock connector for the attachment to a hypodermic needle or an administration set. Attached needle has covered by the protective cap which is intended to provide physical protection to the needle tube. Attached needle may have safety guard that protect the user after use. This product is packed by sterile paper and sterilized by EO gas, and single-use device.

6. Indications for Use:

PLPT LDV (Low Dead Volume) LC(Luer-Cone) Sterile Syringe / PLPT LDV (Low Dead Volume) LL(Luer-Lock) Sterile Syringe 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.

7. Performance data:

1) Bench tests for the device's performance were conducted. Bench testing includes the mechanical testing, sterility testing including EO residues. The tests demonstrated that the device performs in a substantially equivalent manner to the predicate device. The following bench testing is performed to demonstrate the functionality is substantially equivalent.

Test Standard
ISO 7886-1:2017 Sterile hypodermic syringes for single use
ISO 7864:2016 Sterile hypodermic needles for single use
ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices
ISO 80369-7:2021 Small-bore connectors for liquids and gases in healthcare applications

2) Biocompatibility

Biocompatibility of the STERILE SINGLE USE LDV SYRINGE, CHOICARE STERILE SINGLE USE LDV SYRINGE was evaluated in accordance with ISO 10993-1:2018 for the body contact category of "External communication device – Blood path indirect" with a contact duration of "Limited (< 24 hours)". The following tests were performed, as recommended: Cytotoxicity; Skin sensitization; Hemolysis; Intracutaneous reactivity; Acute systemic toxicity; Pyrogenicity. All evaluation acceptance criteria were met.

Test item	Test method / Test criteria
Cytotoxicity test	When it was tested accordingly to ISO 10993-5, tests for in vitro cytotoxicity-Test on extracts method, it should satisfy the requirements.
Hemolysis test	When it was tested accordingly to ISO 10993-4, Selection off tests for interactions with blood-evaluation of hemolytic properties of medical devices and medical device materials, it should satisfy the requirements.
Intracutaneous reactivity test	When it was tested accordingly to ISO 10993-10, Tests for irritation and skin sensitization-Animal intracutaneous (Intradermal) reactivity test, it should satisfy the requirements.
Skin sensitization test	when it was tested accordingly to ISO 10993-10, Tests for irritation and skin sensitization-Guinea pig maximization test (GPMT), it should satisfy the requirements.
Acute systemic toxicity test	When it was tested accordingly to ISO 10993-11, Tests for systemic toxicity-Acute systemic toxicity, it should satisfy the requirements.
Pyrogen Test	When it was tested accordingly to ISO 10993-11, Tests for systemic toxicity-Information on material-mediated pyrogens, it should satisfy the requirements.
LAL Test	USP39 <85>, Bacterial Endotoxins Test
Particulate Matter Injection	USP <788>, Particulate Matter for Injections (Method 1 Light Obscuration Particle Count Test). Test result should satisfy the requirements described in the USP <788>.

3) Sterility and LAL test

The sterilization method has been validated to ISO 11135, which has thereby determined the routine control and monitoring parameters. The testing is performed according to the following standards:

#	Test item	Test standard
1	LAL test	USP39 <85>, Bacterial Endotoxins Test (Unit : EU/Device)
2	E.O sterilization validation	According to ISO 11135:2014 E.O 30%, CO_2 70% Temperature: 50 ±7℃ Exposure time: 5 hours
3	Sterility test	According to ISO 11737-2
4	E.O Residual test	Under the conditions of ISO 10993-7:2008, Ethylene oxide sterilization residuals, the test articles should meet the test requirements.

4) Needle injury test

Test standard
ISO 23908:2011 Sharps injury protection

8. Substantially Equivalent (SE) Comparison

8.1. Syringe

	subject device	Predicate device #1	
Manufacturer	Poonglim Pharmatech Inc.	Poonglim Pharmatech Inc.	Remark

Item	Subject device		Predicate device		
510(K) No.	K221860		K210443		
Indication for use	PLPT LDV (Low Dead Volume) LC(Luer-Cone) Sterile Syringe / PLPT LDV (Low Dead Volume) LL(Luer-Lock) Sterile Syringe 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.		PLPT LDV (Low Dead Volume) Sterile Syringe is intended to be used for medical purpose to inject fluid into or withdraw fluid from body.		Different #1
Components	Barrel, Plunger, Needle (Cannula), Needle hub, Piston, Needle cap, Safety guard		Barrel, Plunger, Piston		Same
Materials	Piston	Rubber	Piston	Rubber	Same
	Plunger	PP	Plunger	PP	
	Barrel	PP	Barrel	PP	
Nozzle type	Luer-lock		Luer-lock, Luer-slip		Different #2
Capacity (Syringe volume)	0.5, 1 mL		1 mL		Different #3
Dead space specification	≤ 0.023mL		≤ 0.023mL		Same
Principle of operation	For Manual Use Only For Single Use Only		For Manual Use Only For Single Use Only		Same
Syringe Performance Requirements	Complies with ISO 7886-1 : 2017 Sterile hypodermic syringes for single use – Part 1 : Syringes for manual use ISO 80369-7 : 2016 Small-bore connector for liquids and gases in healthcare applications – Part 7 : Connectors for intravascular or hypodermic applications		Complies with ISO 7886-1 : 2017 Sterile hypodermic syringes for single use – Part 1 : Syringes for manual use ISO 80369-7 : 2016 Small-bore connector for liquids and gases in healthcare applications – Part 7 : Connectors for intravascular or hypodermic applications		Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Hemolysis Intracutaneous reactivity Bacterial Endotoxins Particulate Matter Injection		Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Acute systemic toxicity Pyrogenicity Sensitization Irritation Hemolysis Intracutaneous reactivity Bacterial Endotoxins Particulate Matter Injection		Same
Sterilization	E.O Gas Sterilized		E.O Gas Sterilized		Same
SAL	10^{-6}		10^{-6}		Same
Endotoxin Limit	20 EU per device		20 EU per device		Same
Principle of operation	The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.		The plunger of syringe can be pulled and pushed along inside the barrel, allowing the syringe to take in and expel the fluids through the connector to the patient.		Same
Label/Labeling	Complied with 21 CFR part 801		Complied with 21 CFR part 801		Same

- **Equivalence discussion**

Different #1 – Indication for Use

The Indications for Use statement for the subject device is not identical to the predicate device; however, the differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the aspiration of fluid from vials, ampoules and liquid injection. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Different #2 – Nozzle Configuration

The configuration of PLPT LDV LC Sterile Syringe is similar as the configuration of predicate device, the

difference is that propose device has luer-cone nozzle type. However, the syringe with luer-cone type is widely used in the clinical. Whether the nozzle type is a luer-cone or luer-lock type, this will not affect the indication for use of the equipment itself. To validate this claim, performance testing was conducted. In accordance to internationally recognized standard(ISO 7886-1), it is proved that nozzle configuration of subject device conforms with relevant standard. Also, requirements per ISO 80369-7 was validated with subject device. Therefore, the differences on configuration do not raise new questions about its safety and/or effectiveness.

Different #3 – Capacity (Syringe Volume)
Although the configuration of PLPT LDV LC/LL Sterile Syringe is similar to the configuration of predicate devices, the capacity of the subject device is different per predicates. However, this change is just in dimension. This difference does not alter the any risks or may rise potential risks per its intended use. Other aspects (e.g., Biocompatibility) are same with the predicates. Performance testing was conducted for this change, and it was confirmed that the differences on configuration do not raise new questions about its safety and effectiveness.

8.2. Needle

	Subject device	**Predicate device #2**	**Remark**
Manufacturer	POONGLIM Pharmatech Inc.	POONGLIM Pharmatech Inc.	Same
510(K) No.	K221860	K210444	N/A
Indication for use	PLPT LDV (Low Dead Volume) LC(Luer-Cone) Sterile Syringe / PLPT LDV (Low Dead Volume) LL(Luer-Lock) Sterile Syringe 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.	This device is intended for use to inject fluids into or withdraw from parts of the body below the surface of the skin	Different #4
Raw Material			Same
Hub of needle	Polypropylene (PP)	Polypropylene (PP)	
Protect cap	Polypropylene (PP)	Polypropylene (PP)	
Cannula	SUS304	SUS304	
Adhesive	Epoxy	Epoxy	
Length	4, 6, 8, 13, 16, 25, 30, 40mm	25 mm	Different #5
Gauge	21, 22, 23, 25, 26, 27, 29, 30, 31, 32, 33, 34G	25G	
Dead space specification	≤0.0054ml	≤0.0054ml	Same
Tip configuration	Bevel	Bevel	Same
Wall type	TW	TW	Same
Needle Performance Requirements	ISO 7864 : 2016 Sterile hypodermic needles for single use — Requirements and test methods ISO 9626 : 2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	ISO 7864 : 2016 Sterile hypodermic needles for single use — Requirements and test methods ISO 9626 : 2016 Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	Same
Safety feature performance Requirements	ISO 23908 : 2011 Sharps Injury Protection - Requirements And Test Methods - Sharps Protection Features For Single-Use Hypodermic Needles, Introducers For Catheters And Needles Used For Blood Sampling	ISO 23908 : 2011 Sharps Injury Protection - Requirements And Test Methods - Sharps Protection Features For Single-Use Hypodermic Needles, Introducers For Catheters And Needles Used For Blood Sampling	Different #6
Biocompatibility	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Cytotoxicity (Hub) Hemolysis test Pyrogen test	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Cytotoxicity (Hub) Hemolysis test Pyrogen test	Same

	Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test LAL test (Endotoxin) Sterility test E.O. Gas Residual	Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test LAL test (Endotoxin) Sterility test E.O. Gas Residual	
Sterilization method	E.O Gas Sterilization	E.O Gas Sterilization	Same
SAL	10^{-6}	10^{-6}	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

- **Equivalence discussion**

Different #4 – Indication for Use

The Indications for Use statement for the subject device is not identical to the predicate device; however, the differences do not alter the intended use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the injecting fluids into or withdraw from parts of the body below the surface of the skin. Therefore, this difference does not affect substantially equivalence on safety and effectiveness.

Different #5 – Needle gauge and length

The overall configuration of PLPT LDV LL/LC Sterile Syringe's needle component is similar as the configuration of predicate device; the difference is that propose device has more variable needle configurations. However, the needle configuration is widely used in the clinical. Whether the different needle configurations are present, this will not affect the indication for use of the equipment itself. To validate this claim, performance testing for the needle component was conducted. In accordance to internationally recognized standard (ISO 7864, ISO 9626), it is proved that needle configuration of proposed device conforms with the relevant standard. Therefore, the differences on configuration do not raise new questions about its safety and/or effectiveness.

Different #6 – Safety features

The safety features for each device are identical with each other. Although the configuration of the needle size (cannula's length, gauge) is more variable compared to the predicate device (K210444), See Different #5), the safety guard's mechanism is not affected by its configurations. The design of the safety feature shows that the safety feature performance is dominated by the linkage between the holding component. For this reason, if the structure of the holding component is identical each device will show exact same performance. Referring to the attached product design, this component's structure is identical, and predicate device's safety feature was tested with ISO 23908 and confirmed that it complies with the standards. Therefore, the subject and predicate device's safety features have the same performance, which is concluded that the difference per the configuration of the needle dimensions does not affect its substantial equivalence on safety and effectiveness.

9. Sterility, Shipping and Shelf-Life

Sterilization validation was performed in accordance with ISO 11135:2014 to prove that the EO Gas sterilization process has been suitable for the continuous production. Through validation, sterilization process was deemed acceptable.

Also, the device's Shelf life of 3 years is validated in accordance with ISO 11607-1:2006 and ISO 11607-2:2006.

10. Substantially Equivalent (SE) Conclusion

The differences between the subject and predicate devices do not raise any new or different questions of safety and effectiveness. As this device is comprised of two predicates, each comparison has been conducted and demonstrated that the specifications and performance of the device are substantially equivalent as the legally marketed predicate devices.