May 29, 2024

Poonglim Pharmatech Inc.
% Peter Chung, President
PlusGlobal
300 Atwood Street
Pittsburgh, Pennsylvania 15213

Re: K241190
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 880.5860
Regulation Name: Piston syringe
Regulatory Class: Class II
Product Code: QNQ, QNS, FMI
Dated: January 19, 2024
Received: April 29, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gang Peng -S

for

Shruti Mistry
Assistant Director
Division of Drug Delivery and General
Hospital Devices, and Human Factors
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241190

Device Name
PLPT LDV(Low Dead Volume) LC(Luer-Cone) Sterile Syringe; PLPT LDV(Low Dead Volume) LL(Luer-Lock) 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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풍림파마텍
POONGLIM Pharmatech Inc.

510(k) Summary
K241190
[as required by 807.92(c)]

1. **Date of Preparation:** May 23, 2024

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: April 29, 2024

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: Piston syringe
   3) Classification name: Low Dead Space Piston Syringe
   4) Product code: QNQ, QNS, FMI
   5) Regulation number: 21 CFR 880.5860
   6) Class of device: Class II
   7) Panel: General hospital

4. **Predicate Device**
   1.1 Predicate device
   1) Trade name (Predicate Submission Number):
   PLPT LDV(Low Dead Volume) LC(Luer-Cone) Sterile Syringe; PLPT LDV(Low Dead Volume) LL(Luer-Lock) Sterile Syringe (K221860)

   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 a 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. 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. The attached needle is covered by the protective cap which is intended to provide physical protection to the needle tube. The attached needle may have a safety guard that protects the user after use. This product is packed by sterile paper and sterilized by EO gas, and is a 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 residuals. The tests demonstrated that the device performs in a substantially equivalent manner to the predicate device. Bench testing was done in accordance with the following standards:
      a. ISO 7886-1:2017 - Sterile hypodermic syringes for single use
      b. ISO 7864:2016 - Sterile hypodermic needles for single use
      c. ISO 9626:2016 - Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
      d. ISO 80369-7:2021- Small-bore connectors for liquids and gases in healthcare applications - Part 7:

2) Biocompatibility

Biocompatibility of the PLPT LDV(Low Dead Volume) LC(Luer-Cone) Sterile Syringe; PLPT LDV(Low Dead Volume) LL(Luer-Lock) Sterile 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	Test result
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.	Pass
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.	Pass
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.	Pass
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.	Pass
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.	Pass
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.	Pass
LAL Test	USP39 <85>, Bacterial Endotoxins Test	Pass
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>.	Pass

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	Test result
1	LAL test	USP39 <85>, Bacterial Endotoxins Test (Unit : EU/Device)	Pass
2	E.O sterilization validation	According to ISO 11135:2014 E.O 30%, CO_2 70% Temperature: 50 ±7℃ Exposure time: 5 hours	Pass
3	Sterility test	According to ISO 11737-2	Pass
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.	Pass

4) Needle injury test

#	Test item	Test standard	Test result
1	Needle penetration force	ISO 23908: 2011 Sharps injury protection	Pass
2	Pull-out force	ISO 23908: 2011 Sharps injury protection	Pass
3	Needle cap removal force	ISO 23908: 2011 Sharps injury protection	Pass
4	Activation (locking) force	ISO 23908: 2011 Sharps injury protection	Pass
5	Unlocking force	ISO 23908: 2011 Sharps injury protection	Pass

8. Substantially Equivalent (SE) Comparison

8.1. Syringe

	Proposed device	Approved device	Remark
Manufacturer	POONGLIM Pharmatech Inc.	POONGLIM Pharmatech Inc.	Same
510(K) No.	K241190	K221860	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.	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.	Same
Classification name	Syringe, Piston	Syringe, Piston	Same
Components	Barrel, Plunger, Plunger rod	Barrel, Plunger, Plunger rod	Same
Dead space specification	≤ 0.023mL with 95% confidence/95% reliability	≤ 0.023mL with 95% confidence/95% reliability	Same
Connection type	Luer-lock, Luer-cone	Luer-lock, Luer-cone	Same
Raw Materials			Same
Plunger rod	PP	PP	
Plunger	Rubber	Rubber	
Barrel	PP	PP	
Capacity (Syringe volume)	0.5, 1, 3, 5, 10 mL	0.5, 1 mL	Difference #1
Sterilization method	E.O Gas Sterilization	E.O Gas Sterilization	Same
SAL	10^{-6}	10^{-6}	Same
Performances	Complies with ISO 7886-1 : 2017 Sterile hypodermic syringes for single use – Part 1 : Syringes for manual use	Complies with ISO 7886-1 : 2017 Sterile hypodermic syringes for single use – Part 1 : Syringes for manual use	Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Hemolysis test Pyrogen test Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test LAL test (Endotoxin) Sterility test E.O. Gas Residual	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Hemolysis test Pyrogen test Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test LAL test (Endotoxin) Sterility test E.O. Gas Residual	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. For Manual Use Only, For Single Use Only	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. For Manual Use Only, For Single Use Only	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same

Equivalence discussion

Difference 1 - Capacity (Syringe Volume)

Although the configuration of PLPT LDV(Low Dead Volume) LC(Luer-Cone) Sterile Syringe; PLPT LDV(Low Dead Volume) LL(Luer-Lock) Sterile Syringe is similar to the configuration of the predicate device, the capacity (syringe volume) of the proposed device is different from the predicate device. However, this change is just in dimension. This difference does not alter the risks or raise potential risks per its intended use. Other aspects (e.g., Biocompatibility) are the same with the predicate device. Performance testing was conducted for this change, and it was confirmed that the differences on configuration do not raise new or different questions of safety and effectiveness when compared to the predicate device.

8.2. Needle

	Proposed device	Approved device	Remark
Manufacturer	POONGLIM Pharmatech Inc.	POONGLIM Pharmatech Inc.	Same
510(K) No.	K241190	K221860	N/A
Indication for use	PLPT LDV (Low Dead Volume) LC(Luer-Cone) Sterile Syringe / PLPT LDV (Low	PLPT LDV (Low Dead Volume) LC(Luer-Cone) Sterile Syringe / PLPT LDV (Low	Same

	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.	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.	
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	4, 6, 8, 13, 16, 25, 30, 40mm	Difference #2
Gauge	18, 21, 22, 23, 25, 26, 27, 29, 30, 31, 32, 33, 34G	21, 22, 23, 25, 26, 27, 29, 30, 31, 32, 33, 34G	
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 specification	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	Same
Biocompatibility	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Cytotoxicity (Hub) Hemolysis test Pyrogen test Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test LAL test (Endotoxin) Sterility test E.O. Gas Residual	Conforms to the requirements of ISO 10993 series standards. Cytotoxicity Cytotoxicity (Hub) Hemolysis test Pyrogen test Intracutaneous reactivity test Skin sensitization test Acute systemic toxicity test LAL test (Endotoxin) Sterility test E.O. Gas Residual	Same
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

Difference #2 – Needle gauge

The overall configuration of PLPT LDV LL/LC Sterile Syringe's needle component is similar as the configuration of the predicate device; the difference is that the subject device has more variable needle configurations. However, the needle configuration is widely used clinically. Performance testing for the needle component was conducted in accordance to internationally recognized standard (ISO 7864, ISO 9626), and the testing shows that the needle configuration of the subject device conforms with the relevant standards. Therefore, the differences in the configuration do not raise new or different questions of safety and/or effectiveness when compared to the predicate device.

9. Sterility, Shipping and Shelf-Life

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

Also, the device's Shelf life of 5 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 when compared to the predicate device. A comparison to the predicate device has been conducted and demonstrated that the specifications and performance of the device are substantially equivalent as the legally marketed predicate device.