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

Re: K210443
Trade/Device Name: PLPT LDV (Low Dead Volume) Sterile Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: Class II
Product Code: QNQ
Dated: February 11, 2021
Received: February 16, 2021

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,

Rumi Young
Acting 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)*
K210443

Device Name
PLPT LDV (Low Dead Volume) Sterile Syringe

Indications for Use *(Describe)*
PLPT LDV (Low Dead Volume) Sterile Syringe is intended to be used for medical purpose to inject fluid into or withdraw fluid from 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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510(K) SUMMARY

Preparation Date:	February 10, 2021
Submitter Name:	POONGLIM Pharmatech Inc. 21, Jayumuyeok 1-gil, Gunsan-si, Jeollabuk-do, Korea
Contact Person:	Peter Chung President, Plus Global
Telephone Number:	412-512-8802
E-mail Address:	peterchung210@gmail.com
Trade Name:	PLPT LDV (Low Dead Volume) Sterile Syringe
Regulation Name:	Piston Syringe
Regulation Number:	21 CFR 880.5860
Product Code:	QNQ
Device Class:	Class II
Predicate Device:	K192551, 1ml Luer Slip or Luer Lock Syringe

Device Description

A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used for injection/withdrawal of fluids/gas (e.g., medication) to/from a medical device or the body (i.e., capable of both); a needle is not included. It is intended for various medical applications and is not dedicated to medication administration. At the distal end of the barrel is a Luer-lock connector for the attachment to a hypodermic needle or an administration set. This is a single-use device.
The PLPT LDV (Low Dead Volume) Sterile Syringe is designed to reduce the fluid waste because of its plunger design.

Indications for Use

PLPT LDV (Low Dead Volume) Sterile Syringe

PLPT LDV (Low Dead Volume) Sterile Syringe is intended to be used for medical purpose to inject fluid into or withdraw fluid from body.

Discussions of differences in Indications for Use statement

The indications for use statement for the subject device is similar to the predicate device.

Technological Characteristics

The table below includes a comparison of the technological characteristics between the new device and those of the predicate device:

Technological Characteristic	**Subject Device** PLPT LDV Sterile Syringe (Poonglim Pharmatech Inc.) K210443	**Predicate Device** 1ml Luer Slip or Luer Lock Syringe (Jiangsu Caina Medical Co., Ltd) K192551	**Comments**

Syringe size	1 ml	1 ml	Same
Connection Type	Luer-lock type	Luer-lock or Luer-slip type	Same
Dead space specification	≤ 0.023mL with 95% confidence/95% reliability	ISO 7886-1 compliant	Comment #1
Materials of Construction	Barrel: PP Plunger rod: PP Plunger: Rubber	Barrel: PP Plunger rod: PP Plunger: Rubber	Comment #2
Sterilization Method	EO gas	EO gas	Same

Discussions of differences in technological characteristics

Comment #1

PLPT LDV (Low Dead Volume) Sterile Syringe is design reduce dead space of the piston syringe. Dead space testing per ISO 7886-1 and analysis of drug delivery capability was provided to verify and validate this change.

Comment #2

PLPT LDV (Low Dead Volume) Sterile Syringe materials of construction are similar to the materials of the predicate. Differences were addressed through biocompatibility testing per ISO 10993-1.

Performance Testing

The device, PLPT LDV Sterile Syringe, described in this summary was tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 7886-1 Second edition: Sterile hypodermic syringes for single use - Part 1: Syringes for manual use
- ISO 10993-1:2018 Biological evaluation of medical devices-Part 1: Evaluation and testing
- ISO 10993-4:2017 Biological evaluation of medical devices-part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009 Biological evaluation of medical devices-Part 5: Test for in vitro cytotoxicity
- ISO 10993-7:2008 Ethylene Oxide sterilization residuals
- ISO 10993-10:2010 Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices-Part 11: Test for systemic toxicity
- ISO 80369-7:2016 Small-bore connectors for liquids and gases in healthcare applications-Part 7: Connectors for intravascular or hypodermic applications
- ASTM F756-17 Standard practice for assessment of hemolytic properties of materials
- USP 39, <71> Sterility Test
- USP 39, <85> Bacterial Endotoxins Test

Additionally, bench testing demonstrating the low dead space capability of the syringe was conducted.

Biocompatibility

In accordance with ISO 10993-1, the syringe is classified as: Externally Communicating Device, Blood Path Indirect, Limited Contact (<24 hours). The following testing results were conformed:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Hemocompatibility

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

Sterility, Shipping and Shelf-Life

- Sterilization validation was performed in accordance with ISO11135:2014 to prove that the EO Gas sterilization process has been suitable for the continuous production. Through validation, sterilization process was deemed acceptable.

- Shelf life of 3 years is validated in accordance with ISO11607-1:2006 and ISO11607-2:2006

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The PLPT LDV Sterile Syringe (Poonglim Pharmatech Inc.) is substantially equivalent to the 1ml Luer Slip or Luer Lock Syringe (Jiangsu Caina Medical Co., Ltd) with respect to the indications for use, target populations, treatment method, and technological characteristics.