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

Re: K210444
Trade/Device Name: EZ-Injec LDV Sterile Safety Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: Class II
Product Code: QNS
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)*
K210444

Device Name
EZ-Injec LDV Sterile Safety Needle

Indications for Use *(Describe)*
This product is intended for use to inject fluid into or withdraw fluids from parts of the body 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

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
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Preparation Date:	February 10, 2021
Trade Name:	EZ-Injec LDV Sterile Safety Needle
Regulation Name:	Hypodermic Single Lumen Needle
Regulation Number:	21 CFR 880.5570
Product Code:	QNS
Device Class:	Class II
Predicate Device:	K192222, EZ-Injec Single Use Needle

Device Description

Sterile single use needle 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 metal tube that is sharpened at one end and at the other end joined to a female connector (hub). The needle cap covers intended to provide physical protection to the needle tube. This product is packed by sterile paper and sterilized by EO gas.
The safety guard is placed around the needle after using the product for safety and to prevent reuse. EZ-Injec LDV Sterile Safety Needle helps to decrease fluid volume loss because of its smaller hub inner size.

	Gauge	**Length**	**Wall Type**
EZ-Injec LDV Sterile Safety Needle	25G	25 mm	TW

Indications for Use

EZ-Injec LDV Sterile Safety Needle
This product is intended for use to inject fluids into or withdraw fluids from parts of the body below the surface of the skin.

Discussions of differences in Indications for Use statement
The indications for use statement for the subject device (EZ-Injec LDV Sterile Safety Needle) is identical 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** EZ-Injec LDV Sterile Safety Needle K210444	**Predicate Device** EZ-Injec Single Use Needle K192222	**Comments**
Gauge	25G	18, 19, 21, 22, 23, 25, 26, 27, 29, 30, 31, 32, 33, 34G	Same
Length	25mm	4, 6, 8, 13, 16, 25, 30, 40mm	Same
Dead space specification	≤0.0054ml	≤0.0544ml (25G-25mm)	See Comment #1
Sharps prevention function	Safety Guard	No Safety Guard	See Comment #2
Hub of needle	Polypropylene (PP)	Polypropylene (PP)	Same
Protector	Polypropylene (PP)	Polypropylene (PP)	Same
Cannula	SUS304	SUS304	Same
Adhesive	Epoxy	Epoxy	Same
Sterilization method	EO gas	EO gas	Same

Discussions of differences in technological characteristics

Comment #1

EZ-Inject LDV sterile safety needle is a modification to the EZ-Inject single use needle (premarket submission no.:K192222). The modification involves a design change to the inner hub to reduce dead space of the needle. Comparative bench testing and analysis of drug delivery capability was provided to verify and validate this change.

Comment #2

EZ-Injec LDV sterile safety needle is a modification to the EZ-Injec single use needle (premarket submission no.: K192222). The modifications involve an addition of the safety guard to protect the user from sharps injuries. This change was validated by bench testing and performed in accordance with ISO 23908.

Performance Testing

The sterile, single lumen hypodermic needles described in this summary were tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 9626 Second edition: Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods
- ISO 7864 Fourth edition: Sterile hypodermic needles for single use - Requirements and test methods
- ISO 23908 First edition: Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

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

Biocompatibility

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

- 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 5 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Conclusions

The differences between the predicate and the subject device do not raise any new or different questions of safety or effectiveness. The EZ-Injec LDV Sterile Safety Needle (K210444) is substantially equivalent to the EZ-Injec Single Use Needle (K192222) with respect to the indications for use, target populations, treatment method, and technological characteristics.