

K221860 PLPT LDV(Low Dead Volume) LC(Luer-Cone) Sterile Syringe, PLPT LDV(Low Dead Volume) LL(Luer-Lock) Sterile SyringeSep 15, 2023
445 days to decisionK221860 · Product code: **QNQ** · General Hospital
Source: <https://www.510kdatabase.net/k221860/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Dead Space Piston Syringe (QNO)
Date received	Jun 27, 2022
Decision date	Sep 15, 2023
Days to decision	445 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Poonglim Pharmatech, Inc.
Location	Gunsan, KR
Contact	Hee Min Cho
510(k) history	6 submissions · 6 cleared · 2018-2024

REGULATORY CONSULTANT

Consulting firm	Plusglobal
Contact	Peter Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026