FDA 510(k) Premarket Notification

CLEARED

K210443 PLPT LDV (Low Dead Volume) Sterile Syringe

Feb 16, 2021

K210443 · Product code: **QNQ** · General Hospital
Source: https://www.510kdatabase.net/k210443/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Dead Space Piston Syringe (QNQ)
Date received	Feb 16, 2021
Decision date	Feb 16, 2021
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Poonglim Pharmatech, Inc.**
Location	Gunsan, KR
Contact	Cho Hee Min
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