

K210444 EZ-Injec LDV Sterile Safety Needle

Feb 16, 2021

K210444 · Product code: **QNS** · General HospitalSource: <https://www.510kdatabase.net/k210444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Dead Space Needle, Single Lumen, Hypodermic (QNS)
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](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k210444/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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