

K192222 EZ-Inject Single use NeedleMay 12, 2020
270 days to decisionK192222 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k192222/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 16, 2019
Decision date	May 12, 2020
Days to decision	270 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192222/> 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 26, 2026