

K212514 Safety Pen Needle for Single Use, Insulin Pen NeedlesApr 29, 2022
262 days to decisionK212514 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k212514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 10, 2021
Decision date	Apr 29, 2022
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Berpu Medical Technology Co., Ltd.
Location	Wenzhou, CN
Contact	Buxin Yu
510(k) history	9 submissions · 9 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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/k212514/> 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