

K253622 Safety Pen NeedleMar 18, 2026
120 days to decisionK253622 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k253622/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 18, 2025
Decision date	Mar 18, 2026
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Medsun Medical Co., Ltd.
Location	Ningbo, CN
Contact	Ping Liu
510(k) history	7 submissions · 7 cleared · 2022-2026

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