

K253605 Safety Heel LancetFeb 20, 2026
94 days to decisionK253605 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Nov 18, 2025
Decision date	Feb 20, 2026
Days to decision	94 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253605/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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