

K244036 Heel Incision Safety Lancet (SteriHeel 2)Feb 26, 2025
58 days to decisionK244036 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k244036/>**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	Dec 30, 2024
Decision date	Feb 26, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SteriLance Medical (Suzhou), Inc.
Location	Suzhou, CN
Contact	Susan Sun
510(k) history	8 submissions · 8 cleared · 2016-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k244036/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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