

**K221521 Disposable Safety Lancet**Oct 28, 2022  
156 days to decisionK221521 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	May 25, 2022
Decision date	Oct 28, 2022
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221521/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026