

K210745 Heel Incision Safety LancetAug 26, 2021
167 days to decisionK210745 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210745/>**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	Mar 12, 2021
Decision date	Aug 26, 2021
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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