

K233796 Disposable safety lancet (Impress)Jan 16, 2024
48 days to decisionK233796 · Product code: **FMK** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233796/>**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 29, 2023
Decision date	Jan 16, 2024
Days to decision	48 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Disposable safety lancet (Impress Pro); Disposable safety lancet (Lite4); Disposable blood lancet (Elite); Disposable blood lancet (Elite Pro)

APPLICANT

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

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