FDA 510(k) Premarket Notification

CLEARED

K244036 Heel Incision Safety Lancet (SteriHeel 2)

Feb 26, 2025
58 days to decision

K244036 · Product code: **FMK** · General & Plastic Surgery
Source: 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