

K243533 Sterilized Eol Auto LancetJan 13, 2025
59 days to decisionK243533 · Product code: **FMK** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243533/>**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 15, 2024
Decision date	Jan 13, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sterilized Eol Lancet Plus

APPLICANT

Company	Hlb Co., Ltd. Healthcare
Location	Sejong-Si, KR
Contact	Seung-won Baek
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	SMB Korea Co.
Contact	Kyung-hwan Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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