FDA 510(k) Premarket Notification

K242680 LetsGetChecked Impress

CLEARED

Jan 13, 2025
129 days to decision

K242680 · Product code: **FMK** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242680/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Single Use Only Blood Lancet With An Integral Sharps Injury Prevention Feature (FMK)
Date received	Sep 6, 2024
Decision date	Jan 13, 2025
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Privapath Diagnostics Ltd (Dba Letsgetchecked)**
Location	Dublin, IE
Contact	Karen Walsh
510(k) history	1 submissions · 0 cleared · 2025-2025