

K261829 Profoject™ Dual-Safety Pen Needles

Jul 29, 2026
57 days to decision

K261829 · Product code: FMI · General Hospital
Source: <https://www.510kdatabase.net/k261829/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 2, 2026
Decision date	Jul 29, 2026
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CMT Health PTE., Ltd.
Location	Singapore, SG
Contact	Monica Ma
510(k) history	10 submissions · 10 cleared · 2025-2026