FDA 510(k) Premarket Notification

CLEARED

K260739 Profoject™ Pen Needles (Model A

Jul 15, 2026
131 days to decision

K260739 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k260739/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 6, 2026
Decision date	Jul 15, 2026
Days to decision	131 days
Third-party review	No
Summary / Statement	Summary
Other names	Model B)

APPLICANT

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