

K260855 Profoject™ Safety Pen NeedlesJun 10, 2026
86 days to decisionK260855 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k260855/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 16, 2026
Decision date	Jun 10, 2026
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CMT Health PTE., Ltd.
Location	Singapore, SG
Contact	Monica Ma
510(k) history	8 submissions · 8 cleared · 2025-2026

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