

K260514 Profoject™ Safety NeedleJun 12, 2026
115 days to decisionK260514 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k260514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Feb 17, 2026
Decision date	Jun 12, 2026
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary
Other names	Profoject™ Syringe with Safety Needle; Profoject™ Low Dead Space Syringe with Safety Needle

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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