

K252033 Profoject™ Disposable Syringe, Profoject™ Disposable Syringe with NeedleJul 25, 2025
25 days to decisionK252033 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k252033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jun 30, 2025
Decision date	Jul 25, 2025
Days to decision	25 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CMT Health PTE., Ltd.
Location	Singapore, SG
Contact	Monica Ma
510(k) history	6 submissions · 6 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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