

**K253068 Profoject™ Insulin Syringes**Feb 23, 2026  
154 days to decisionK253068 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k253068/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 22, 2025
Decision date	Feb 23, 2026
Days to decision	154 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Profoject™ Safelock Disposable Insulin Syringe

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Third Party Review Group, LLC</b>
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)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253068/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026