

**K252631 Profoject™ Disposable Needle**Oct 16, 2025  
57 days to decisionK252631 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k252631/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 20, 2025
Decision date	Oct 16, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252631/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026