

**K250658 SureFine Pen Needle**Apr 3, 2025  
29 days to decisionK250658 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k250658/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 5, 2025
Decision date	Apr 3, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Shina Med Corporation</b>
Location	Anseong-Si, KR
Contact	Taejoo Ha
510(k) history	7 submissions · 7 cleared · 2016-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Plusglobal</b>
Contact	Peter Chung

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250658/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026