FDA 510(k) Premarket Notification

K250658 SureFine Pen Needle

CLEARED

Apr 3, 2025
29 days to decision

K250658 · 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	**Shina Med Corporation**
Location	Anseong-Si, KR
Contact	Taejoo Ha
510(k) history	7 submissions · 7 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	**Plusglobal**
Contact	Peter Chung

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