FDA 510(k) Premarket Notification

K250510 Sure-Fine Insulin Syringes

CLEARED

Oct 15, 2025
236 days to decision

K250510 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k250510/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Feb 21, 2025
Decision date	Oct 15, 2025
Days to decision	236 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