

K250700 Pen Injector Needle 32.5Nov 21, 2025
259 days to decisionK250700 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k250700/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 7, 2025
Decision date	Nov 21, 2025
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corporation
Location	Shibuya-Ku, Tokyo, JP
Contact	Brian Byrd
510(k) history	13 submissions · 13 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	Terumo Medical Corporation
Contact	Brian Byrd

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250700/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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