FDA 510(k) Premarket Notification

K250284 TSK SELECT™ Needle

CLEARED

Jul 24, 2025
174 days to decision

K250284 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k250284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 31, 2025
Decision date	Jul 24, 2025
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tsk Laboratory, Japan**
Location	Tochigi-Ken, JP
Contact	Yumi Ueda
510(k) history	3 submissions · 3 cleared · 1997-2025

REGULATORY CONSULTANT

Consulting firm	**Namsa**
Contact	Anna Galea

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k250284/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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