FDA 510(k) Premarket Notification

K243309 27G x 1/2 TW K-Pack Surshield Needle (KN-S2713RBT)

CLEARED

May 29, 2025
220 days to decision

K243309 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k243309/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 21, 2024
Decision date	May 29, 2025
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Europe N.V.**
Location	Leuven, BE
Contact	Liesbeth Decoster
510(k) history	28 submissions · 28 cleared · 1999-2025