

K243309 27G x 1/2 TW K-Pack Surshield Needle (KN-S2713RBT)May 29, 2025
220 days to decisionK243309 · Product code: **FMI** · General HospitalSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243309/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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