

K243581 K-Pack Enhance Needle (KH-2713RBBTC and KH-2913RBBTC)Apr 4, 2025
141 days to decisionK243581 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k243581/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 14, 2024
Decision date	Apr 4, 2025
Days to decision	141 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

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