

**K251447 K-Pack Embrace Active Safety Needle (KNAS-2516RB, KNAS-2525RB)**Jul 8, 2025  
60 days to decisionK251447 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k251447/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 9, 2025
Decision date	Jul 8, 2025
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251447/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026