CLEARED

K251447 K-Pack Embrace Active Safety Needle (KNAS-2516RB, KNAS-2525RB)

Jul 8, 2025
60 days to decision

K251447 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k251447/

SUBMISSION DETAILS

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

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