

K984576 K-PACK II (HYPODERMIC NEEDLE) 23G X 1, MODEL KN-2325RB, K-PACK II NEEDLE (HYPODERMIC NEEDLE) 25G X 1, MODEL KN-2525RB, KJun 14, 1999
173 days to decisionK984576 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k984576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 23, 1998
Decision date	Jun 14, 1999
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Europe N.V.
Location	Leuven, BE
Contact	M J AERTS
510(k) history	28 submissions · 28 cleared · 1999-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984576/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026