

K082820 K-PACK II NEEDLE - 29G THIN WALLOct 23, 2008
28 days to decisionK082820 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k082820/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 25, 2008
Decision date	Oct 23, 2008
Days to decision	28 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/k082820/> 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 24, 2026