FDA 510(k) Premarket Notification

K150263 K-Pack II Needle-21G x 2

CLEARED

Apr 1, 2015
56 days to decision

K150263 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k150263/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 4, 2015
Decision date	Apr 1, 2015
Days to decision	56 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.net
Device record: https://www.510kdatabase.net/k150263/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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