

**K110527 K-PACK SURSHIELD NEEDLE, HYPODERMIC NEEDLE
FOR SINGLE USE**Jun 6, 2011
102 days to decisionK110527 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k110527/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 24, 2011
Decision date	Jun 6, 2011
Days to decision	102 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

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