

**K111797 27 G X 1/2 K-PACK SURSHIELD NEEDLE**Sep 22, 2011  
90 days to decisionK111797 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k111797/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 24, 2011
Decision date	Sep 22, 2011
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111797/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 18, 2026