

**K151398 K-Pack II Needle - 29G x 5/16 Thin Wall**Jun 25, 2015  
30 days to decisionK151398 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k151398/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 26, 2015
Decision date	Jun 25, 2015
Days to decision	30 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/k151398/> 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 May 14, 2026