

**K250724 Intraosseous Infusion Needles**Jul 30, 2025  
142 days to decisionK250724 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k250724/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 10, 2025
Decision date	Jul 30, 2025
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spectrum Vascular</b>
Location	White Plains, NY, US
Contact	Sharon Klugewicz
510(k) history	4 submissions · 4 cleared · 2024-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250724/> 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 13, 2026