

**K250255 xvision Spine system**Mar 13, 2025  
44 days to decisionK250255 · Product code: **SBF** · Orthopedic  
Source: <https://www.510kdatabase.net/k250255/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Jan 28, 2025
Decision date	Mar 13, 2025
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Augmedics, Ltd.</b>
Location	Yokneam Illit, IL
Contact	Tami Harel
510(k) history	6 submissions · 6 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250255/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026