

K251639 xvision Spine systemOct 3, 2025
127 days to decisionK251639 · Product code: **SBF** · Orthopedic
Source: <https://www.510kdatabase.net/k251639/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	May 29, 2025
Decision date	Oct 3, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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