

K241481 xvision Spine SystemOct 16, 2024
145 days to decisionK241481 · Product code: **SBF** · Orthopedic
Source: <https://www.510kdatabase.net/k241481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	May 24, 2024
Decision date	Oct 16, 2024
Days to decision	145 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 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)

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