

K261854 xvision Spine system

Jul 31, 2026
58 days to decision

K261854 · Product code: **SBF** · Orthopedic
Source: <https://www.510kdatabase.net/k261854/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Jun 3, 2026
Decision date	Jul 31, 2026
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Augmedics, Ltd.
Location	Yokneam Illit, IL
Contact	Tami Harel
510(k) history	7 submissions · 7 cleared · 2019-2026