FDA 510(k) Premarket Notification

K211188 xvision Spine system (XVS)

CLEARED

Jul 19, 2021
90 days to decision

K211188 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k211188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Apr 20, 2021
Decision date	Jul 19, 2021
Days to decision	90 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