FDA 510(k) Premarket Notification

K220905 xvision Spine System

CLEARED

Nov 17, 2022
234 days to decision

K220905 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k220905/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Mar 28, 2022
Decision date	Nov 17, 2022
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Augmedics, Ltd.**
Location	Yokneam Illit, IL
Contact	Contact Title
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