

K211254 ARAI Surgical Navigation SystemJan 14, 2022
263 days to decisionK211254 · Product code: **SBF** · Orthopedic
Source: <https://www.510kdatabase.net/k211254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Apr 26, 2021
Decision date	Jan 14, 2022
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Surgalign Spine Technologies
Location	Deerfield, IL, US
Contact	Cristian Luciano
510(k) history	3 submissions · 3 cleared · 2022-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211254/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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