

**K212904 SeaSpine WaveForm C Interbody System**Dec 14, 2021  
92 days to decisionK212904 · Product code: **OVE** · Orthopedic  
Source: <https://www.510kdatabase.net/k212904/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Sep 13, 2021
Decision date	Dec 14, 2021
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SeaSpine Orthopedics Corporation</b>
Location	Carlsbad, CA, US
Contact	Hong Phan
510(k) history	66 submissions · 66 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212904/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026