

**K193418 SeaSpine Skipjack System**Mar 13, 2020  
95 days to decisionK193418 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k193418/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Dec 9, 2019
Decision date	Mar 13, 2020
Days to decision	95 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>SeaSpine Orthopedics Corporation</b>
Location	Carlsbad, CA, US
Contact	Aly Alvarez
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/k193418/> 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 15, 2026