

**K193106 SpineFrontier Lumbar Interbody Fusion Device System**Jun 19, 2020  
224 days to decisionK193106 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k193106/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Nov 8, 2019
Decision date	Jun 19, 2020
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spinefrontier, Inc.</b>
Location	Beverly, MA, US
Contact	Vito Lore
510(k) history	24 submissions · 24 cleared · 2007-2020

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193106/> 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 June 15, 2026