

**K190193 SpineEX Sagittae® Lateral Lumbar Interbody Fusion Devices**Mar 4, 2019  
28 days to decisionK190193 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k190193/>**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	Feb 4, 2019
Decision date	Mar 4, 2019
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spineex, Inc.</b>
Location	Fremont, CA, US
Contact	Andrew Rogers
510(k) history	3 submissions · 3 cleared · 2018-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Empirical Testing Corp</b>
Contact	Meredith Lee May

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190193/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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