

**K181531 SpineEX Sagittae Lateral Lumbar Interbody Fusion Devices**Oct 5, 2018  
116 days to decisionK181531 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k181531/>**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         | Jun 11, 2018   |
| Decision date         | Oct 5, 2018  |
| Days to decision      | 116 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](https://accessdata.fda.gov)

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