

**K171495 Zyston Strut Open Titanium Spacer System**Feb 12, 2018  
266 days to decisionK171495 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k171495/>**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	May 22, 2017
Decision date	Feb 12, 2018
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer Biomet Spine, Inc.</b>
Location	Broomfield, CO, US
Contact	Megan Fessenden
510(k) history	15 submissions · 15 cleared · 2017-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171495/> 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 26, 2026