

**K170399 Endoskeleton TO Interbody Fusion Device (IBD)**Jul 6, 2017  
147 days to decisionK170399 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k170399/>**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	Feb 9, 2017
Decision date	Jul 6, 2017
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Titan Spine, LLC</b>
Location	Mequon, WI, US
Contact	Jane Rodd
510(k) history	14 submissions · 14 cleared · 2008-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k170399/> 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 16, 2026