

**K180990 TirboLOX-L Lumbar IBFD**Aug 13, 2018  
119 days to decisionK180990 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k180990/>**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	Apr 16, 2018
Decision date	Aug 13, 2018
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Captiva Spine, Inc.</b>
Location	Pleasant Grove, UT, US
Contact	Jackie Ferro
510(k) history	8 submissions · 8 cleared · 2009-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180990/> 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 18, 2026