

**K212811 Ti3Z Lumbar Interbody System**Apr 12, 2022  
221 days to decisionK212811 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k212811/>**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	Sep 3, 2021
Decision date	Apr 12, 2022
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zavation Medical Products, LLC</b>
Location	Flowood, MS, US
Contact	Katie Motley
510(k) history	30 submissions · 30 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212811/> 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 14, 2026