

**K182210 TiWAVE-L Porous Titanium Lumbar Cage**Jan 7, 2019  
145 days to decisionK182210 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k182210/>**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	Aug 15, 2018
Decision date	Jan 7, 2019
Days to decision	145 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kalitec Medical, LLC</b>
Location	Orlando, FL, US
Contact	Scott Winn
510(k) history	2 submissions · 2 cleared · 2019-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182210/> 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 27, 2026