

**K152355 Twin Peaks Lumbar Interbody Fusion System**Dec 10, 2015  
112 days to decisionK152355 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k152355/>**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 20, 2015
Decision date	Dec 10, 2015
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Spineway</b>
Location	Ecully, FR
Contact	Julien Thao my
510(k) history	5 submissions · 5 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152355/> 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