

**K223413 Pisces™-SA STANDALONE ALIF Interbody System**Feb 10, 2023  
93 days to decisionK223413 · Product code: **OVD** · Orthopedic  
Source: <https://www.510kdatabase.net/k223413/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Nov 9, 2022
Decision date	Feb 10, 2023
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Osseus Fusion Systems</b>
Location	Dallas, TX, US
Contact	Jonathan Rosen
510(k) history	5 submissions · 5 cleared · 2019-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Jalex Medical, LLC</b>
Contact	Jennifer Palinchik

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223413/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026