

K213935 PISCES-SA Standalone ALIF Interbody SystemMay 6, 2022
141 days to decisionK213935 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k213935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Dec 16, 2021
Decision date	May 6, 2022
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Jalex Medical, LLC
Contact	Daniel Johnson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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