

K253266 Titanium Interbody SystemJan 8, 2026
101 days to decisionK253266 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k253266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 29, 2025
Decision date	Jan 8, 2026
Days to decision	101 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spine Innovation, LLC
Location	Solana Beach, CA, US
Contact	Jude Paganelli
510(k) history	2 submissions · 2 cleared · 2016-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253266/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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