

K253260 ORIO-3D Cage SystemApr 16, 2026
199 days to decisionK253260 · Product code: **ODP** · Orthopedic
Source: <https://www.510kdatabase.net/k253260/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Cervical (ODP)
Date received	Sep 29, 2025
Decision date	Apr 16, 2026
Days to decision	199 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	SpineCraft
Location	Westmont, IL, US
Contact	Ami Akallal-Asaad
Website	https://spinecraft.com
510(k) history	3 submissions · 3 cleared · 2009-2026

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