

K254202 MectaLIF 3D Metal AnteriorMay 5, 2026
127 days to decisionK254202 · Product code: **OVD** · Orthopedic
Source: <https://www.510kdatabase.net/k254202/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Lumbar (OVD)
Date received	Dec 29, 2025
Decision date	May 5, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medacta International S.A.
Location	Castel San Pietro, CH
Contact	Stefano Baj
Website	https://www.medacta.com
510(k) history	165 submissions · 165 cleared · 2008-2026

REGULATORY CONSULTANT

Consulting firm	Medacta USA
Contact	Christopher Lussier

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

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