

K200551 MectaLIF Transforaminal TiPEEKFeb 12, 2021
346 days to decisionK200551 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k200551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 3, 2020
Decision date	Feb 12, 2021
Days to decision	346 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medacta Inernational SA
Location	Castel San Pietro (Ch), CH
Contact	Stefano Baj
510(k) history	4 submissions · 4 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Medacta USA
Contact	Chris 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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