

K192906 Mecta-C Stand AloneMar 4, 2020
141 days to decisionK192906 · Product code: **OVE** · Orthopedic
Source: <https://www.510kdatabase.net/k192906/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Intervertebral Fusion Device With Integrated Fixation, Cervical (OVE)
Date received	Oct 15, 2019
Decision date	Mar 4, 2020
Days to decision	141 days
Third-party review	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	164 submissions · 164 cleared · 2008-2026

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