

K203335 MectaScrew ExtensionFeb 3, 2022
448 days to decisionK203335 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k203335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Nov 12, 2020
Decision date	Feb 3, 2022
Days to decision	448 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	164 submissions · 164 cleared · 2008-2026

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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