

**K231483 MySpine Unilateral Guides**Jul 21, 2023  
59 days to decisionK231483 · Product code: **PQC** · Orthopedic  
Source: <https://www.510kdatabase.net/k231483/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pedicle Screw Placement Guide (PQC)
Date received	May 23, 2023
Decision date	Jul 21, 2023
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medacta International S.A.</b>
Location	Castel San Pietro, CH
Contact	Stefano Baj
Website	<a href="https://www.medacta.com">https://www.medacta.com</a>
510(k) history	164 submissions · 164 cleared · 2008-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medacta USA</b>
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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