

**K250477 NextAR(TM) Spine**Jul 31, 2025  
162 days to decisionK250477 · Product code: **SBF** · Orthopedic  
Source: <https://www.510kdatabase.net/k250477/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Feb 19, 2025
Decision date	Jul 31, 2025
Days to decision	162 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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