

**K232280 NextAR™ TSA Platform**Oct 29, 2023  
90 days to decisionK232280 · Product code: **SBF** · Orthopedic  
Source: <https://www.510kdatabase.net/k232280/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Jul 31, 2023
Decision date	Oct 29, 2023
Days to decision	90 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	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)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232280/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026