

**K193559 NextAR TKA Platform**Jul 10, 2020  
200 days to decisionK193559 · Product code: **SBF** · Orthopedic  
Source: <https://www.510kdatabase.net/k193559/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Dec 23, 2019
Decision date	Jul 10, 2020
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medacta International SA</b>
Location	Castel San Pietro (Ch), CH
Contact	Stefano Baj
510(k) history	4 submissions · 4 cleared · 2020-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193559/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026