FDA 510(k) Premarket Notification

# K250477 NextAR(TM) Spine

**CLEARED**

Jul 31, 2025
162 days to decision

K250477 · 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

| | |
|---|---|
| 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

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|---|---|
| Consulting firm | **Medacta USA** |
| Contact | Christopher Lussier |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov