FDA 510(k) Premarket Notification

K233172 NextAR™ Spine Platform

CLEARED

Apr 24, 2024
209 days to decision

K233172 · Product code: **SBF** · Orthopedic
Source: https://www.510kdatabase.net/k233172/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthopedic Augmented Reality (SBF)
Date received	Sep 28, 2023
Decision date	Apr 24, 2024
Days to decision	209 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

Consulting firm	**Medacta USA**
Contact	Chris Lussier

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