FDA 510(k) Premarket Notification

CLEARED

K231911 Glenoid Reconstruction System – Full Wedge Baseplate

Nov 9, 2023
133 days to decision

K231911 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k231911/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jun 29, 2023
Decision date	Nov 9, 2023
Days to decision	133 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