FDA 510(k) Premarket Notification

CLEARED

K252404 Comprehensive Reverse Shoulder - HA Glenosphere Baseplates

Apr 15, 2026
258 days to decision

K252404 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k252404/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Jul 31, 2025
Decision date	Apr 15, 2026
Days to decision	258 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biomet Orthopedics**
Location	Warsaw, IN, US
Contact	Julie Gantenberg
510(k) history	4 submissions · 4 cleared · 2020-2026