FDA 510(k) Premarket Notification

K260583 Equinoxe® Shoulder System

CLEARED

Apr 14, 2026
53 days to decision

K260583 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k260583/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Feb 20, 2026
Decision date	Apr 14, 2026
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Exactech, Inc.**
Location	Gainesville, FL, US
Contact	Pedro Ravelo
510(k) history	186 submissions · 174 cleared · 1986-2026

REGULATORY CONSULTANT

Consulting firm	**Advita Ortho**
Contact	Pedro Ravelo

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