

K260583 Equinoxe® Shoulder SystemApr 14, 2026
53 days to decisionK260583 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260583/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026