

K243448 Equinoxe® Shoulder SystemAug 1, 2025
267 days to decisionK243448 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k243448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Nov 7, 2024
Decision date	Aug 1, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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