

**K150458 Exactech Equinox Reverse Shoulder 46x21mm
Glenosphere**May 14, 2015
80 days to decisionK150458 · Product code: **PHX** · Orthopedic
Source: <https://www.510kdatabase.net/k150458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Feb 23, 2015
Decision date	May 14, 2015
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	Thomas McNamara
Website	https://www.exac.com/
510(k) history	186 submissions · 174 cleared · 1986-2026

Exactech, Inc. operates with a manufacturing facility in Gainesville, US. The company does not offer direct sales or distribution in the United States. Product inquiries and safety concerns are handled through designated company contacts. Exactech has submitted FDA 510(k) applications, resulting in cleared devices. The company's regulatory activity spans from 1986 to 2026, demonstrating sustained engagement with FDA clearance processes. Orthopedic devices represent the dominant focus of the company's portfolio, accounting for approximately 99% of submissions. Recent FDA 5...

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Device record: <https://www.510kdatabase.net/k150458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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