

**K182536 Exactech Equinox Small Reverse Shoulder
Glenospheres , Exactech Equinox Reverse Shoulder Humeral
Liners , Exactech Equinox Small Reverse Shoulder Glenoid
Plates , Exactech Equinox Reverse Shoulder Locking Cap**Oct 12, 2018
28 days to decisionK182536 · Product code: PHX · Orthopedic
Source: <https://www.510kdatabase.net/k182536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shoulder Prosthesis, Reverse Configuration (PHX)
Date received	Sep 14, 2018
Decision date	Oct 12, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Exactech, Inc.
Location	Gainesville, FL, US
Contact	Zach Sharrah
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...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182536/> 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 16, 2026